IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Applicants: SHANKS, Steven C. and TUCEK, Kevin B.
Title of Invention: Multi-Probe Device
Filed: July 1, 2003
Serial Number: 10/612,504
Atty Docket No.: 206-038

Examiner: Henry M. Johnson, III
Art Unit: 3739

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Sandra L. Etherton

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SUPPLEMENTAL APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

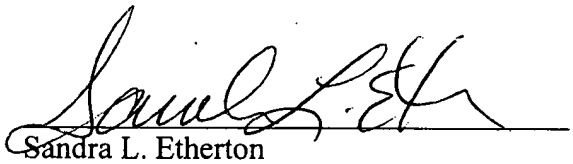
A Notice of Appeal/Request for Reinstatement of Appeal was filed January 29, 2007 which subsequently requires an appeal brief to be filed within two months. This Appeal Brief is timely submitted within two months of the Request for Reinstatement of Appeal. Applicants believe no fees are due.

The following documents are enclosed:

- Supplemental Appeal brief (35 sheets)
- Claims Appendix (6 sheets)
- Appendix E-1 (4 sheets including cover)
- Appendix RP (15 sheets including cover)
- Appendix R-1 (18 sheets including cover)

Appendix R-3

- Appendix R-2 (7 sheets)
- Appendix R-3 (19 sheets)
- Appendix R-4 (8 sheets)
- Appendix R-5 (46 sheets)
- Appendix R-6 (16 sheets)



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VII. Argument

Cases Cited

In re Fulton, 391 F. 3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004)

In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987)

In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966)

In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983)

Hansgirg v. Kemmer, 40 USPQ 665 (CCPA 1939)

In re King, 231 USPQ 136 (Fed. Cir. 1986)

In re Oelrich and Divigard, 212 USPQ 323 (CCPA 1981)

In re Oeticker, 977, F.2d 1443, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992)

In re Ratti, 123 USPQ 349 (CCPA 1959)

In re Rijckaert, 28 USPQ2nd 1955 (Fed. Cir. 1993)

In re Rouffet, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998)

MEHL/Biophile Int'l Corp. v. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999)

Verdegaal Brothers, Inc. v. Union Oil Company of California, 2 USPQ2d 1051 (Fed. Cir. 1987)

List of References

R-1 Applicants' Specification and Drawings of U.S. Patent Application No. 10/612,504, as amended (referred to herein as the "Pending App.")

R-2 U.S. Patent 6,074,411 issued to Lai (referred to herein as "Lai")

R-3 U.S. Patent 6,267,779 issued to Gerdes (referred to herein as "Gerdes")

R-4 Office action dated November 10, 2005

R-5 Appeal Brief dated August 2, 2006

R-6 U.S. patent 5,653,706 issued to Zavislan (referred to herein as "Zavislan")

Copies of the references above are included in the References Cited Appendix

Manual of Patent Examining Procedure, Eighth Edition, August 2001, Rev. 4 October 2005

MPEP §2112.02

MPEP §2141.01(a)

MPEP §2142

MPEP §2143.01

MPEP §2146

I. Real Party in Interest

The real parties in interest are the inventors, Steven C. Shanks and Kevin B. Tucek.

Appellants note that, in the event a terminal disclaimer is required to avoid a double-patenting type obviousness rejection, upon a notice of allowance and assuming such terminal disclaimer is still required, Applicants will file a terminal disclaimer and an assignment fully complying with 37 CFR § 1.321 and 37 CFR § 3.73. In such case, the real parties in interest will now include Therapy Products, Inc. dba Erchonia Medical (formed as a result of the merger between Therapy Products, Inc. and Erchonia Medical, Inc), owned in the majority by the inventors.

II. Related Appeals and Interferences

No appeals or interferences are pending which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal, however the following are, or were, copending patent applications or litigation related to the application on appeal:

Type	Application or Patent Number	How Related to Application on Appeal	Atty Docket Number
US Patent	6,605,079	this patent claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-001
US Patent	09/932,907 now U.S. Pat. No 6,746,473	this application claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-002
PCT Application	PCT/US2002/019359	PCT application, and national stage applications and issued patents therefrom, claim the benefit of the common priority application US Pat. Application No. 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-021
CIP of related application	10/772,973	this application claims the benefit of common priority application U.S. Application No. 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-024
CIP of related application	10/772,738	this patent application claims the benefit of common priority application U.S. Application No.	206-032

		09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	
judicial proceeding in Federal District Court of Colorado*	04-MK-1769 (CBS)	litigation alleging infringement of U.S. Pat. No 6,746,473 and invalidity thereof, et alia. U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-066
CIP of Patent Application on appeal	11/443980	this application claims the benefit of the application on appeal, which claims benefit of the common priority application 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-071
DIV of Patent Application on appeal	11/431257	this application claims the benefit of the application on appeal, which claims benefit of the common priority application 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-133

* A Markman hearing was held in Colorado District Court action 04-MK-1769 (CBS) to construe certain claims of U..S Patent No. 6,746,473, which claims the benefit of common priority application 09/932,907, now U.S. Pat. No. 6,746,473. That decision is attached in the Related Proceedings Appendix as Appendix RP-1. No other decisions have been rendered by a court or the Board in any proceeding identified under this section.

III. Status of the Claims

Claims 1-10, 13-30, and 32 of U.S. Patent Application No. 10/612,504 are pending and stand rejected twice and constitute the subject matter of this appeal. Claims 11-12, 31, 33 -34 have been cancelled. Claims 35-39 were withdrawn by the Examiner.

IV. Status of Amendments

Applicants proposed amendments subsequent to the final office action dated November 10, 2005. Those amendments were considered, but not entered, by the Examiner.

Claim amendments made in response to an office action dated June 3, 2005 were entered by the Examiner in an office action dated November 10, 2005. Those amended claims constitute the subject matter of this appeal and appear in the Claims Appendix.

V. Summary of Claimed Subject Matter

In U.S. Patent Application No. 10/612,504, the Applicants present a single laser device that enables a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. paragraphs [0005], [0006], [0007] and [0024] and Fig. 7. This is an improvement over prior art because earlier devices could not freely treat different areas of a patient at the same time.

The claimed device also enables a practitioner to personally and freely treat a patient using multiple laser beam emissions each with a specific spot shape, such as a line. Pending App. paragraphs [0018], lines 1-3. This has the advantage of enabling the practitioner to more precisely define the surface area the laser impinges upon. A copy of Applicants' specification, as amended, and drawings are enclosed for easy reference as Appendix R-1. The claims on appeal are listed in the Claims Appendix.

A. Independent Claim 1

Claim 1 defines a device (Pending App. paragraph [0015], line 1) having two or more handheld probes (Pending App. paragraph [0015], line 4). Each of the probes houses one or more laser energy sources (Pending App. paragraph [0016], lines 1-3) and each laser energy source produces a laser beam that is shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph 0017, lines 1-3). Each probe is moved freely by the user while the laser beams are being emitted (Pending App. paragraphs [0015] and [0024]; Fig. 7).

B. Independent Claim 23

Claim 23 generally defines the same device as claim 1, except that it specifies that the laser energy sources must be semiconductor laser diodes and adds a control circuit for controlling the laser beams. Specifically, Claim 23 covers a laser device (Pending App. paragraph [0015], line 1) having first and second handheld probes (Pending App. paragraph [0015], line 4). Each of the probes has a semiconductor diode (Pending App. paragraph [0022], lines 3-7) laser energy source (Pending App. paragraph [0016], lines 1-3), and each laser energy source produces a laser beam that is shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph [0017], lines 1-3). There is a control circuit for independently controlling each of the laser beams (Pending App. paragraph [0020], lines 1-9). Each probe is freely moved by the user's hand relative to the surface of the skin of a patient while emitting the first laser beam (Pending App. Paragraphs [0015] and [0024]; Fig. 7).

C. Independent Claim 30

Claim 30 generally defines the same device as claim 1 except that it specifies that each laser beam emits a different wavelength of visible light. Specifically, Claim 30 covers a device having two or more laser energy sources (Pending App. paragraph [0016], lines 1-3) housed in two or more handheld probes (Pending App. paragraph [0015], line 4). Each laser beam emits a visible wavelength (Pending App. paragraph [0022], lines 2-8) shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph [0017], lines 1-3). Each probe can be moved freely by the user while the laser beams are being emitted (Pending App. Paragraphs [0015] and [0024]; Fig. 7).

None of the claims on appeal recite means-plus-function limitations.

VI. Grounds of Rejection to be Reviewed on Appeal

A. Are Claims 1, 2, 8-10, 13-15, 22, 30 and 32 unpatentable under 35 USC 102(b) as being anticipated by U.S. Patent 6,074,411 issued to Lai?

B. Are Claims 3-7, 16-22, and 23-29 unpatentable under 35 USC 103(a) as being obvious in light U.S. Patent 6,074,411 issued to Lai in view of U.S. Patent 6,267,779 issued to Gerdes?

C. Are Claims 1-10, 13-14, 17, 18, 21, and 23-27 unpatentable as double-patenting claims 1-11 and 13 of U.S. Patent 6,746,473 issued to Shanks and Tucek?

D. Are Claims 1-10, 13-30, and 32 unpatentable under 35 USC 103(a) as being obvious in light of U.S. Patent 6,267,779 issued to Gerdes in view of U.S. Patent 5,653,706 issued to Zavislan et al?

VII. Argument

A. Lai Does Not Anticipate Applicants' Claims under 35 USC 102(b).

Appellants incorporate by reference their arguments presented in section VII.A. at pp. 15-22 of their original Appeal Brief, filed August 2, 2006 and attached hereto as Appendix R-5.

B. Applicants' Claims are Not Obvious Under 35 USC 103(a) in light of U.S. Patent 6,074,411 issued to Lai in view of U.S. Patent 6,267,779 issued to Gerdes.

Appellants incorporate by reference their arguments presented in section VII.B. at pp. 16-34 of their original Appeal Brief, filed August 2, 2006 and attached hereto as Appendix R-5.

C. Claims 1-10, 13-14, 17, 18, 21, and 23-27 Cannot be Actually Rejected for Double-Patenting Because Claims Are Not Yet Otherwise Allowable.

Appellants incorporate by reference their arguments presented in section VII.C. at p.35 of their original Appeal Brief, filed August 2, 2006 and attached hereto as Appendix R-5.

D. Applicant's Claims are Not Obvious Under 35 USC 103(a) in light of U.S. Patent 6,267,779 issued to Gerdes in view of U.S. Patent 5,653,706 issued to Zavislan et al.

Legal Standard for Obviousness

In order to determine whether an invention is obvious in light of prior art, the Patent Office should make several basic factual inquiries, including the scope and content of the prior art. *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). The scope of the prior art should include only analogous prior art. MPEP §2141.01(a). In general, in order for a reference to be considered analogous prior art, the reference must either be in

the field of applicant's endeavor or, if not, be reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oeticker*, 977 F.2d 1443, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). Moreover, it is also necessary that a person of ordinary skill, seeking to solve a particular problem, would reasonably be expected or motivated to look to the allegedly analogous technology. *Id.*, 24 USPQ2d at 1446.

In addition to limiting prior art to only analogous art, to establish *a prima facie* case of obviousness, there also must be some suggestion or motivation to modify the reference or combine the teachings. MPEP §2142; *In re Rouffet,* 149 F.3d 1350, 1356, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998); *In re Geiger,* 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). The references must be considered as a whole, and there must be something in the prior art as a whole to suggest the desirability of the combination. MPEP §2142; *In re Fulton*, 391 F 3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004). Moreover, it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125,1127 (Fed. Cir. 1984). *See also* MPEP §2146; *In re Grasselli, 218 USPQ 769, 779 (Fed. Cir. 1983)*; *In re Ratti*, 123 USPQ 349, 352, CCPA 1959.

1. Claims 1-10 and 13-22 are not obvious in light of Gerdes and Zavislan because Zavislan is non-analogous art.

Each of Applicants' claims 1-10 and 13-22 are directed at low-power therapeutic handheld laser probes that are freely moved by a user's hands for healing purposes. While Zavislan teaches a single handheld laser device, it teaches one in an entirely different field and solving an unrelated problem. It is well-settled law that it is improper to consider a reference that is non-analogous. *In re Oeticker,* 24 USPQ2d at 1446.

Applicant's invention is a handheld multi-probe non-ablative laser device for wound healing, edema reduction, pain relief, inflammation reduction, and other similar applications. Pending App. Paragraph [0003], lines 2-6. It uses low-level laser energy and causes no immediate detectable temperature rise and no macroscopically visible changes in tissue structure. Pending App. Paragraph [0004], lines 2-4. The treated and surrounding tissue is neither heated nor damaged. *Id.* Additionally, because no damage occurs where the laser beam is applied, more than one laser can be applied simultaneously for faster and improved therapy. Pending App. Paragraph [0005], lines 1-6.

Zavislan discloses a high-power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device uses thermolysis (from thermo- meaning heat and -lysis meaning break down), which is defined as a decomposition or dissociation of chemical compounds by use of heat. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 30-35. A laser treatment with the device disclosed in Zavislan necessarily causes a rise in temperature and changes in tissue structure to accomplish necrosis and cauterization. *Id*. In addition, particular attention to visualizing where the laser beam is applied is critical according to Zavislan so that the operator does not damage areas where no treatment is desired. Zavislan, column 2, lines 16-18.

Because therapeutic lasers and surgical lasers result in dramatically different results on a patient's body, they must be designed considering different parameters and

safety concerns. Accordingly, high-power single-probe ablative lasers requiring precise aiming are not in the same field of endeavor as multi-probe low-energy therapeutic laser therapy devices.

Additionally, Applicants' invention solves the problem of how to apply multiple low-level laser beams to a patient simultaneously and with freely movable handheld probes. Zavislan's invention does not teach or suggest any solutions because it cannot operate safely or successfully if expanded to multiple handheld probes. Ablative lasers require the operator to pay particular attention to aiming the laser beam at a single tiny treatment area, making it physically impossible to apply more than one ablative laser beam at a time. Otherwise, the operator would inadvertently damage areas not intended to be treated with a first laser while attending to the desired treatment area of a second laser. Only in the movies can a human aim and fire two laser weapons simultaneously at two different microscopic targets and hit them. It would not be reasonable for Applicants to consider destructive technology that is incapable of supporting multi-probe devices when designing a therapeutic multi-probe device.

Because Zavislan involves different types of lasers and because a low-level laser device designer would not look to high-power ablative lasers when designing a multi-probe device, Zavislan is non-analogous art. Accordingly, no *prima facie* case of obviousness has been established.

2. Claims 1-10 and 13-22 are not obvious in light of Gerdes and Zavislan because Zavislan teaches away from using more than one handheld probe.

Each of Applicants' claims 1-10 and 13-22 teaches a device comprising two or more handheld laser probes. Although Gerdes teaches multiple handheld wands,

Zavislan teaches away from multiple wands. It is well-settled law that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Zavislan discloses a high power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. Because Zavislan's device causes temperature changes and structural changes in tissue, particular attention to visualizing where the laser beam is applied is critical. As stated in Zavislan:

> It is the principal object of the present invention to provide an improved system for laser assisted microsurgical ... treatments in which the treatment area can be visualized while the laser beam is being located at sites in the area where treatment is desired.

Zavislan, column 2, lines 14-18. It would be impractical, possibly even dangerous, to attempt to apply multiple ablative laser beams simultaneously. Zavislan teaches a device specifically designed to allow the operator to visually aim the laser beam. Zavislan's ablative laser device will fail if it is expanded to multiple handheld probes, especially where they treat different areas simultaneously.

Accordingly, Zavislan teaches away from using multiple handheld laser probes. Because references cannot be combined where one reference teaches away from the combination, Zavislan and Gerdes cannot be combined. No *prima facie* case of obviousness has been established.

3. Claims 1-10 and 13-22 are not obvious in light of Gerdes and Zavislan because the prior art teaches against freely moving the probes.

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Each of Applicants' claims 1-10 and 13-22 teach handheld probes that "emit one or more laser beams ... while being freely moved by a user's hand relative to the surface of the skin of a patient." Gerdes and Zavislan each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. See Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically for the laser beams to intersect, the wands must be treating the same area of the patient. It would render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

As explained above, Zavislan teaches a device wherein the wand is visually positioned over a treatment area where microsurgery is desired. Because Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath, it is critical to aim the laser beam accurately. Zavislan, column 1, lines 24-30 and column 2, lines 14-18. It would be

impractical, possibly even dangerous, to freely move one or more ablative laser beams during treatment.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from moving the probes freely, Gerdes and Zavislan cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

4. Claim 2 is not obvious in light of Gerdes and Zavislan because the prior art teaches against emitting two laser beams simultaneously and impinging two different parts of a patient's body.

Applicants' Claim 2 requires that "at least two of the laser beams are emitted simultaneously and impinge two different parts of a patient's body." As detailed earlier, Applicants' intend that their invention enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Gerdes and Zavislan each teach away from simultaneously treating two different parts of a patient's body, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Again, Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. See Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically for the laser beams to intersect, the wands must be treating the same area of the patient. It would render Gerdes inoperable to modify it such that two laser beams simultaneously

treat different areas of a patient because then the laser beams would not intersect. Thus, Gerdes teaches against the probes simultaneously treating two different areas of a patient's body.

Again, Zavislan teaches a device wherein the wand is visually positioned over a treatment area where microsurgery is desired. Because Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath, it is critical to visually aim the laser beam accurately. Zavislan, column 1, lines 24-30 and column 2, lines 14-18. It would render Zavislan inoperable to modify it such that two ablative laser beams treat two different areas simultaneously because then the operator could not visually aim the laser beams. Thus, Zavislan teaches against the probes simultaneously treating two different areas of a patient's body.

Because it is improper to combine references when on teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from simultaneously treating two different parts of the body with two laser beams, Gerdes and Zavislan cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

5. Claim 16 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests using ultraviolet laser light.

Applicants' claim 16 claims at least one laser energy source generating a laser beam having a wavelength in the ultraviolet range. Ultraviolet light ranges from about 4 nm to 380 nm, just beyond violet in the visible spectrum of light. Neither Gerdes nor

Zavislan disclose or suggest generating a laser beam having a wavelength in the ultraviolet range.

Zavislan discloses exposing tissue to laser beams having a wavelength from 700 to 1300 nm. Zavislan, column 3, lines 57-60. Zavislan does not disclose or suggest a wavelength of less than 700 nm.

Gerdes discloses exposing tissue to converging beams of treatment (infrared) radiation having a wavelength of between approximately 900 nm and 1100 nm. Gerdes also discloses aiming (visible) radiation having a wavelength of between approximately 400 nm and 700 nm. Gerdes, column 8, lines 53-55; column 9, lines 35-39; column 12, lines 53-60; and all claims. Gerdes does not disclose a wavelength of less than 400 nm.

The Examiner alleges on page 4 of his September 28th, 2006 office action that Gerdes discloses 400nm of ultraviolet light at col. 9, line 38. Gerdes actually refers to *visible* light at 400 nm, however. Specifically, the Gerdes cite reads in its entirety:

> Additionally, each of the *visible* laser radiation sources 170 is also configured to emit radiation having a wavelength preferably between approximately 400 nm to approximately 700 nm, and more preferably between about 635 nm and about 640 nm.

Gerdes at column 9, lines 34-39 (emphasis added). Ultraviolet light is not visible light. Therefore, Gerdes does not suggest an ultraviolet wavelength.

Because each reference affirmatively discloses an operating range and does not disclose operations in the ultraviolet range and because neither the nature of the problem to be solved nor the teachings of Zavislan suggests the use of ultraviolet wavelengths, neither Zavislan nor Gerdes suggests using an ultraviolet wavelength. Lacking any

suggestion or motivation for an ultraviolet wavelength, no *prima facie* case of obviousness has been made.

6. Claim 17 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests a linear spot shape.

Applicants' claim 17 requires one of the spot shapes to be substantially linear. Zavislan does not disclose any particular beam shapes. Moreover, while Gerdes discloses that "a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patterns are also suitable for use with the present invention," a line is not a "spread-out" spot shape in the same sense. See Gerdes, column 9, lines 45-49. The light of Gerdes's "spread out patterns" travel in all directions in the plane of the treatment surface. A linear spot shape, however, is not "spread out" because it travels in only one direction in the plane of the treatment surface, namely along the length of the line. Therefore, Gerdes does not disclose or suggest a line. Lacking any suggestion or motivation of a linear beam shape, no *prima facie* case of obviousness has been made.

7. Claim 19 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests a plus-sign spot shape.

Applicants' claim 19 requires one of the spot shapes to be in the shape of a plus sign. Zavislan does not disclose any particular beam shapes. Moreover, while Gerdes discloses that "a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patters are also suitable for use with the present invention," a plus-sign is not a "spread-out" spot shape. See Gerdes, column 9, lines 45-49. Lacking any suggestion or motivation of a plus-sign spot shape, no *prima facie* case of obviousness has been made.

8. Claim 21 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests different spot shapes.

Applicants' claim 21 requires that the spot shape of a first laser beam to be different from a spot shape of a second laser beam; that is, the first and second beam shapes are different. Again, Zavislan does not disclose any particular beam shapes. While Gerdes discloses that "a wide variety" of "spread-out" beam shapes can be used, Gerdes does not indicate that the beam shapes emitted from the radiation sources can be different from each other. See Gerdes, column 9, lines 45-49. Lacking any suggestion or motivation of two different beam shapes, no *prima facie* case of obviousness has been made.

9. Claims 23-29 are not obvious in light of Gerdes and Zavislan because Zavislan is non-analogous art.

Each of Applicants' claims 23-29 are directed at low-power healing handheld laser probes that are freely moved by a user's hands for healing purposes. While Zavislan teaches a single handheld laser device, it teaches one in an entirely different field and solving an unrelated problem. It is well-settled law that it is improper to consider a reference that is non-analogous. *In re Oeticker,* 24 USPQ2d at 1446.

Applicant's invention is a handheld multi-probe non-ablative laser device for wound healing, edema reduction, pain relief, inflammation reduction, and other similar applications. Pending App. Paragraph [0003], lines 2-6. It uses low-level laser energy and causes no immediate detectable temperature rise and no macroscopically visible changes in tissue structure. Pending App. Paragraph [0004], lines 2-4. The treated and surrounding tissue is neither heated nor damaged. *Id.* Additionally, because no damage occurs where the laser beam is applied, more than one laser can be applied

simultaneously for faster and improved therapy. Pending App. Paragraph [0005], lines 1-6. Precise and accurate aiming of each probe is not critical to successful therapeutic results.

Zavislan discloses a high-power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. A laser treatment with the device disclosed in Zavislan necessarily causes changes a rise in temperature and changes in tissue structure to accomplish necrosis and cauterization. *Id*. In addition, particular attention to visualizing where the laser beam is applied is critical according to Zavislan so that the operator does not damage areas where no treatment is desired. Zavislan, column 2, lines 16-18.

Because therapeutic lasers and surgical lasers result in dramatically different results on a patient's body, they must be designed considering different parameters and safety concerns. Accordingly, high-power single-probe ablative lasers requiring precise aiming are not in the same field of endeavor as multi-probe low-energy therapeutic laser therapy devices.

Additionally, Applicants' invention solves the problem of how to apply multiple low-level laser beams to a patient simultaneously and with freely movable handheld probes. Zavislan's invention does not teach or suggest any solutions because it cannot operate safely or successfully if expanded to multiple handheld probes. The arguments of Section VII.D.2 are incorporated herein. Ablative lasers require the operator to pay particular attention to aiming the laser beam accurately, making it impossible to apply

more than one ablative laser beam at a time. It would not be reasonable for Applicants to consider destructive technology incapable of supporting multi-probe devices when designing a multi-probe therapeutic device.

Because Zavislan involves different types of lasers and because a low-level laser device designer would not look to high-power ablative lasers when designing a multi-probe device, Zavislan is non-analogous art. Accordingly, no *prima facie* case of obviousness has been established.

10. Claims 23-29 are not obvious in light of Gerdes and Zavislan because Zavislan teaches away from using more than one handheld probe.

Each of Applicants' claims 23-29 teaches a device comprising two or more handheld laser probes. Although Zavislan teaches multiple handheld wands, Zavislan teaches away from multiple wands. It is well-settled law that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Zavislan discloses a high power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. Because Zavislan's device causes temperature changes and structural changes in tissue, particular attention to visualizing where the laser beam is applied is critical. As stated in Zavislan:

> It is the principal object of the present invention to provide an improved system for laser assisted microsurgical ... treatments in which the treatment area can be visualized while the laser beam is being located at sites in the area where treatment is desired.

Zavislan, column 2, lines 14-18. It would be impractical, possibly even dangerous, to attempt to apply multiple ablative laser beams simultaneously. Zavislan teaches a device specifically designed to allow the operator to visually aim the laser beam. Zavislan's ablative laser device will fail if it is expanded to multiple handheld probes, especially where they treat different areas simultaneously.

Accordingly, Zavislan teaches away from using multiple handheld laser probes. Because references cannot be combined where one reference teaches away from the combination, Zavislan and Gerdes cannot be combined. No *prima facie* case of obviousness has been established.

11. Claims 23-29 are not obvious in light of Gerdes and Zavislan because the prior art teaches against freely moving the probes.

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Each of Applicants' claims 23-29 teach handheld probes that "emit one or more laser beams ... while being freely moved by a user's hand relative to the surface of the skin of a patient." Gerdes and Zavislan each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. See Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically for the laser beams to intersect, the wands must be treating the same area of the patient. It would

render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

Zavislan teaches a device wherein the wand is visually positioned over a treatment area where microsurgery is desired. Because Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath, it is critical to aim the laser beam accurately. Zavislan, column 1, lines 24-30 and column 2, lines 14-18. It would be impractical, possibly even dangerous, to freely move multiple ablative laser beams during treatment.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from moving the probes freely, Gerdes and Zavislan cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

12. Claim 29 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests using ultraviolet laser light.

Applicants' claim 29 claims at least one laser energy source generating a laser beam having a wavelength in the ultraviolet range. Ultraviolet light ranges from about 4 nm to 380 nm, just beyond violet in the visible spectrum of light. Neither Gerdes nor Zavislan disclose or suggest generating a laser beam having a wavelength in the ultraviolet range.

Zavislan discloses exposing tissue to laser beams having a wavelength from 700 to 1300 nm. Zavislan, column 3, lines 57-60. Zavislan does not disclose or suggest a wavelength of less than 700 nm.

Gerdes discloses exposing tissue to converging beams of treatment (infrared radiation having a wavelength of between approximately 900 nm and 1100 nm. Gerdes also discloses aiming (visible) radiation having a wavelength of between approximately 400 nm and 700 nm. Gerdes column 8, lines 53-55; column 9, lines 35-39; column 12, lines 53-60; and all claims. Gerdes does not disclose a wavelength of less than 400 nm.

The Examiner alleges on page 4 of his September 28, 2006 office action that Gerdes discloses 400nm of ultraviolet light at col. 9, line 38. Gerdes actually refers to *visible* light at 400 nm, however. Specifically, the Gerdes cite reads in its entirety:

> Additionally, each of the *visible* laser radiation sources 170 is also configured to emit radiation having a wavelength preferably between approximately 400 nm to approximately 700 nm, and more preferably between about 635 nm and about 640 nm.

Gerdes at column 9, lines 34-39 (emphasis added). Ultraviolet light is not visible light. Therefore, Gerdes does not suggest an ultraviolet wavelength.

Because each reference affirmatively discloses an operating range and does not disclose operations in the ultraviolet range and because neither the nature of the problem to be solved nor the teachings of Zavislan suggests the use of ultraviolet wavelengths, neither Zavislan nor Gerdes suggests using an ultraviolet wavelength. Lacking any suggestion of motivation for an ultraviolet wavelength, no *prima facie* case of obviousness has been made.

13. Claims 30 and 32 are not obvious in light of Gerdes and Zavislan because Zavislan is non-analogous art.

Each of Applicants' claims 30 and 32 are directed at low-power healing handheld laser probes that are freely moved by a user's hands for healing purposes. While Zavislan teaches a single handheld laser device, it teaches one in an entirely different field and solving an unrelated problem. It is well-settled law that it is improper to consider a reference that is non-analogous. *In re Oeticker,* 24 USPQ2d at 1446.

Applicant's invention is a handheld multi-probe non-ablative laser device for wound healing, edema reduction, pain relief, inflammation reduction, and other similar applications. Pending App. Paragraph [0003], lines 2-6. It uses low-level laser energy and causes no immediate detectable temperature rise and no macroscopically visible changes in tissue structure. Pending App. Paragraph [0004], lines 2-4. The treated and surrounding tissue is neither heated nor damaged. *Id.* Additionally, because no damage occurs where the laser beam is applied, more than one laser can be applied simultaneously for faster and improved therapy. Pending App. Paragraph [0005], lines 1-6. Precise and accurate aiming of each probe is not critical to successful therapeutic results.

Zavislan discloses a high-power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. A laser treatment with the device disclosed in Zavislan necessarily causes changes in tissue structure and temperature rises. In addition, particular attention to visualizing where the laser beam is applied is critical

according to Zavislan so that the operator does not damage areas where no treatment is desired. Zavislan, column 2, lines 16-18.

Because therapeutic lasers and surgical lasers result in dramatically different results on a patient's body, they must be designed considering different parameters and safety concerns. Accordingly, high-power single-probe ablative lasers requiring precise aiming are not in the same field of endeavor as multi-probe low-energy therapeutic laser therapy devices.

Additionally, Applicants' invention solves the problem of how to apply multiple low-level laser beams to a patient simultaneously and with freely movable handheld probes. Zavislan's invention does not teach or suggest any solutions because it cannot operate safely or successfully if expanded to multiple handheld probes. Ablative lasers require the operator to pay particular attention to aiming and focusing the laser beam accurately, making it impossible to apply more than one ablative laser beam at a time. It would not be reasonable for Applicants to consider technology incapable of supporting multi-probe devices when designing a therapeutic device for treating multiple areas simultaneously with non-ablative lasers.

Because Zavislan involves different types of lasers and because a low-level laser device designer would not look to high-power ablative lasers when designing a multi-probe device, Zavislan is non-analogous art. Accordingly, no *prima facie* case of obviousness has been established.

14. Claims 30 and 32 are not obvious in light of Gerdes and Zavislan because Zavislan teaches away from using more than one handheld probe.

Each of Applicants' claims 30 and 32 teaches a device comprising two or more handheld laser probes. Although Zavislan teaches multiple handheld wands, Zavislan teaches away from multiple wands. It is well-settled law that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Zavislan discloses a high power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. Because Zavislan's device causes temperature changes and structural changes in tissue, particular attention to visualizing where the laser beam is applied is critical. As stated in Zavislan:

> It is the principal object of the present invention to provide an improved system for laser assisted microsurgical ... treatments in which the treatment area can be visualized while the laser beam is being located at sites in the area where treatment is desired.

Zavislan, column 2, lines 14-18. It would be impractical, possibly even dangerous, to attempt to apply multiple ablative laser beams simultaneously. Zavislan teaches a device specifically designed to allow the operator to visually aim the laser beam. Zavislan's ablative laser device will fail if it is expanded to multiple handheld probes, especially where they treat different areas simultaneously.

Accordingly, Zavislan teaches away from using multiple handheld laser probes. Because references cannot be combined where one reference teaches away from the

combination, Zavislan and Gerdes cannot be combined. No *prima facie* case of obviousness has been established.

15. Claims 30 and 32 are not obvious in light of Gerdes and Zavislan because the prior art teaches against freely moving the probes.

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Each of Applicants' claims 30 and 32 teach handheld probes that "emit one or more laser beams ... while being freely moved by a user's hand relative to the surface of the skin of a patient." Gerdes and Zavislan each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. See Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically for the laser beams to intersect, the wands must be treating substantially the same area of the patient. It would render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

Zavislan teaches a device wherein the wand is visually positioned over a treatment area where microsurgery is desired. Because Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath, it is critical to aim the laser beam accurately. Zavislan, column 1,

lines 24-30 and column 2, lines 14-18. It would be impractical, possibly even dangerous, to freely move one or more ablative laser beams during treatment.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from moving the probes freely, Gerdes and Zavislan cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

Conclusion

Applicants have shown that Claims 1-10, 13-30, and 32 are not obvious under 35 USC 103(a) in light of Gerdes and Zavislan for one or more reasons explained above. Reversal of the rejections is respectfully requested.

VIII. Conclusion

Applicants believe they have shown that none of the Examiner's rejections in the pending application should be sustained. Applicants respectfully request that the Board reverse all the Examiner's rejections and allow the case to proceed to issuance.

Respectfully submitted,

Date: 3/4/07

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(12) **United States Patent**
Gerdes

(10) **Patent No.: US 6,267,779 B1**
(45) **Date of Patent: Jul. 31, 2001**

(54) **METHOD AND APPARATUS FOR THERAPEUTIC LASER TREATMENT**

(75) Inventor: **Harold M. Gerdes**, Peninsula, OH (US)

(73) Assignee: **MedeLaser, LLC**, West Palm Beach, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/281,443**

(22) Filed: **Mar. 29, 1999**

(51) **Int. Cl.**[7] **A61N 5/00**
(52) **U.S. Cl.** **607/89**; 606/3
(58) **Field of Search** 606/2, 3, 9–15; 607/88, 89

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Passarella et al., "Certain Aspects of Helium–Neon Laser Irradiation on Biological Systems in Vitro," *Ibid* at pp. 67–74.

"Low–Intensity Laser Reduces Arthritis Symptoms" by Pfieiffer in the *Journal of Clinical Laser Medicine & Surgery*, vol. 10, No. 6, (1992).

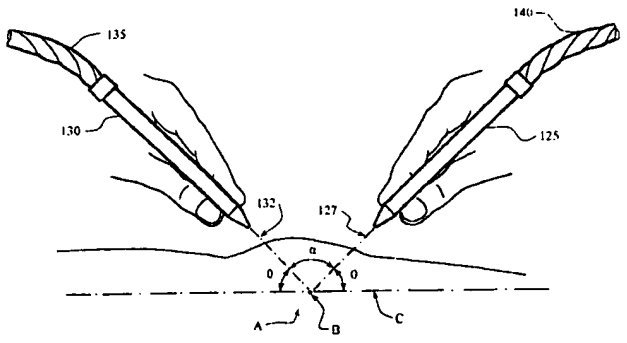
In a research report by Beckerman et al. entitled: "The Efficacy of Laser Therapy for Musculoskeletal and Skin Disorders: A Criteria–Based Meta–analysis of Randomized Clinical Trials", *Physical Therapy*, vol. 72, No. 7, Jul., 1992.

Primary Examiner—Michael Peffley
(74) *Attorney, Agent, or Firm*—Sean M. Casey

(57) **ABSTRACT**

The therapeutic laser apparatus includes at least two wands connected to a controller and radiation source via fiber optic cables. The controller and source include at least two infrared wavelength solid-state diode ("SSD") lasers and at least two visible wavelength SSD aiming lasers. The apparatus further includes a combiner configured to maintain the electromagnetic radiation from one infrared SSD laser coincident with one visible light SSD aiming laser. In the method according to the invention, the visible light SSD aiming laser is used as a pointer so that an operator can position the wands adjacent to the skin of a mammal whereby the beams of infrared treatment lasers intersect at a region inside the body of the mammal.

30 Claims, 8 Drawing Sheets



Appendix R-4

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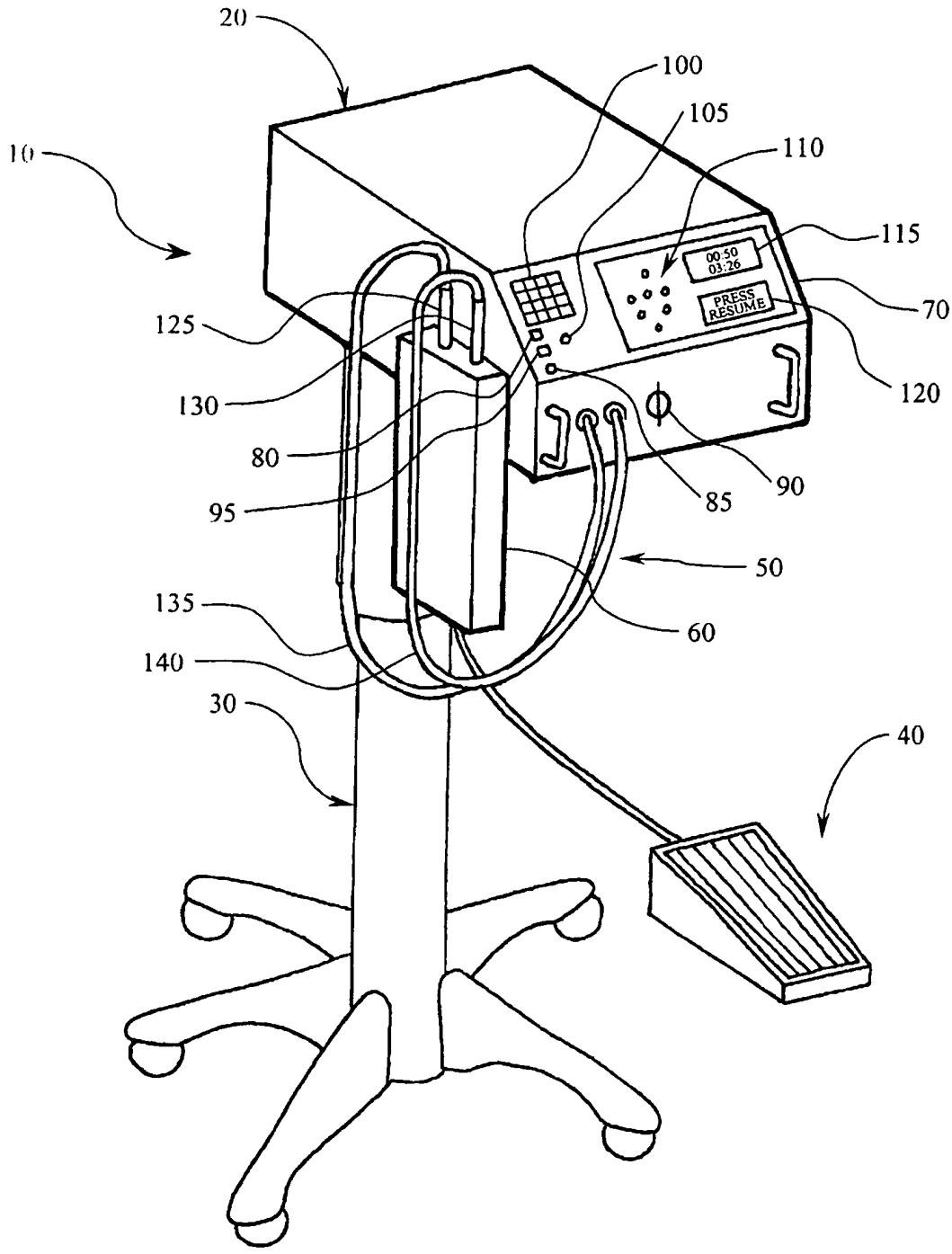
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FIG. 1

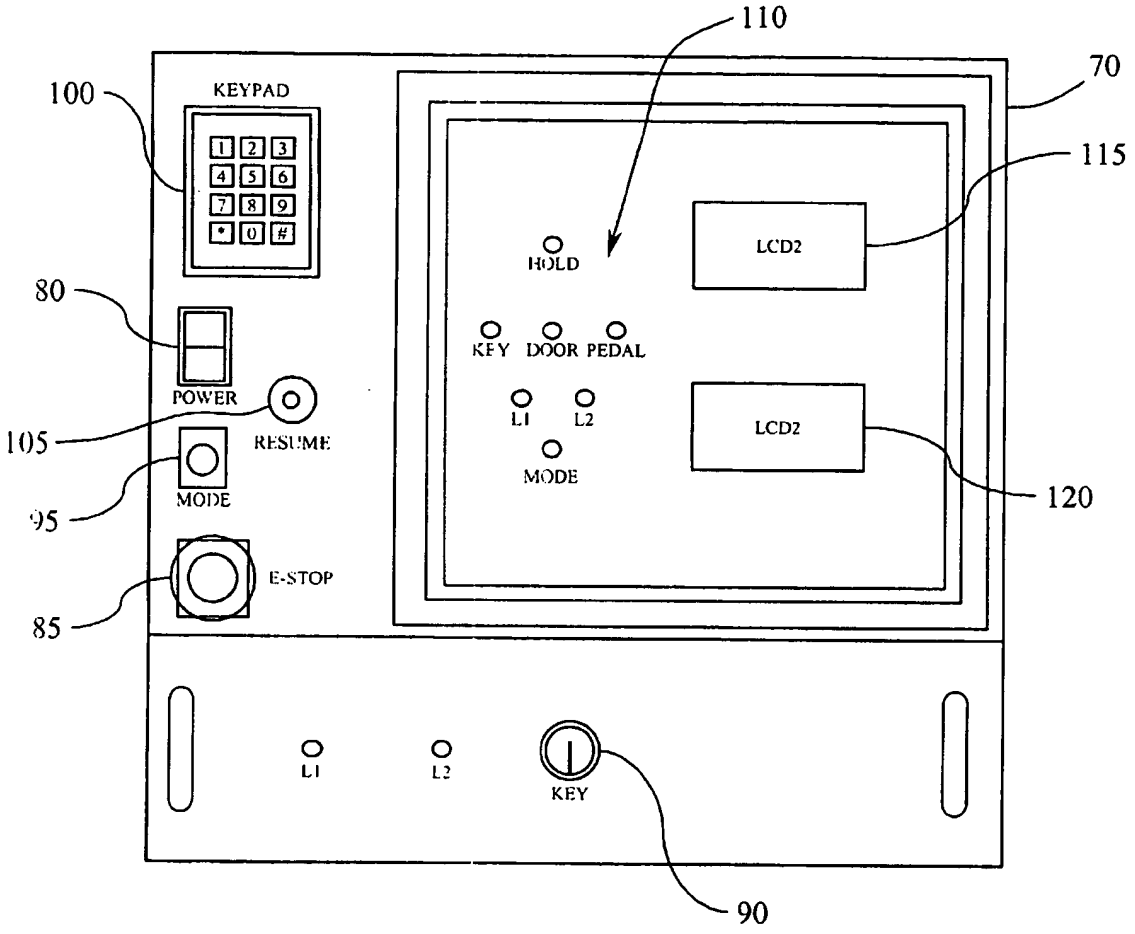
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FIG. 2

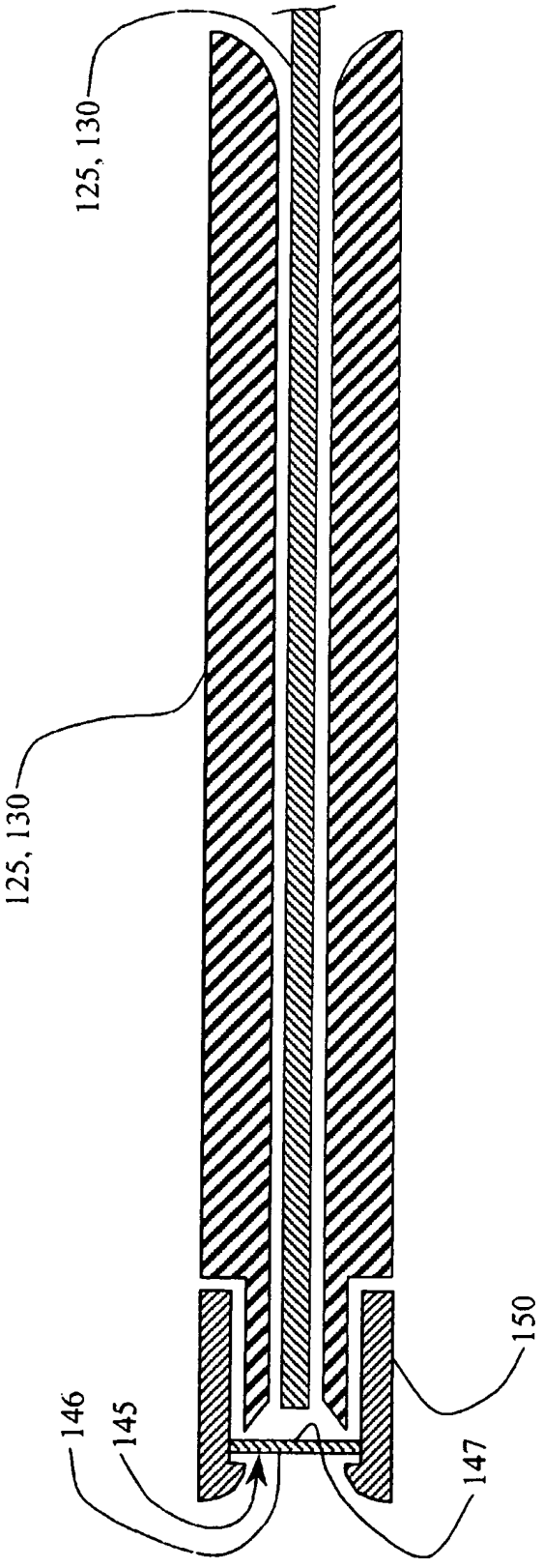

FIG. 3

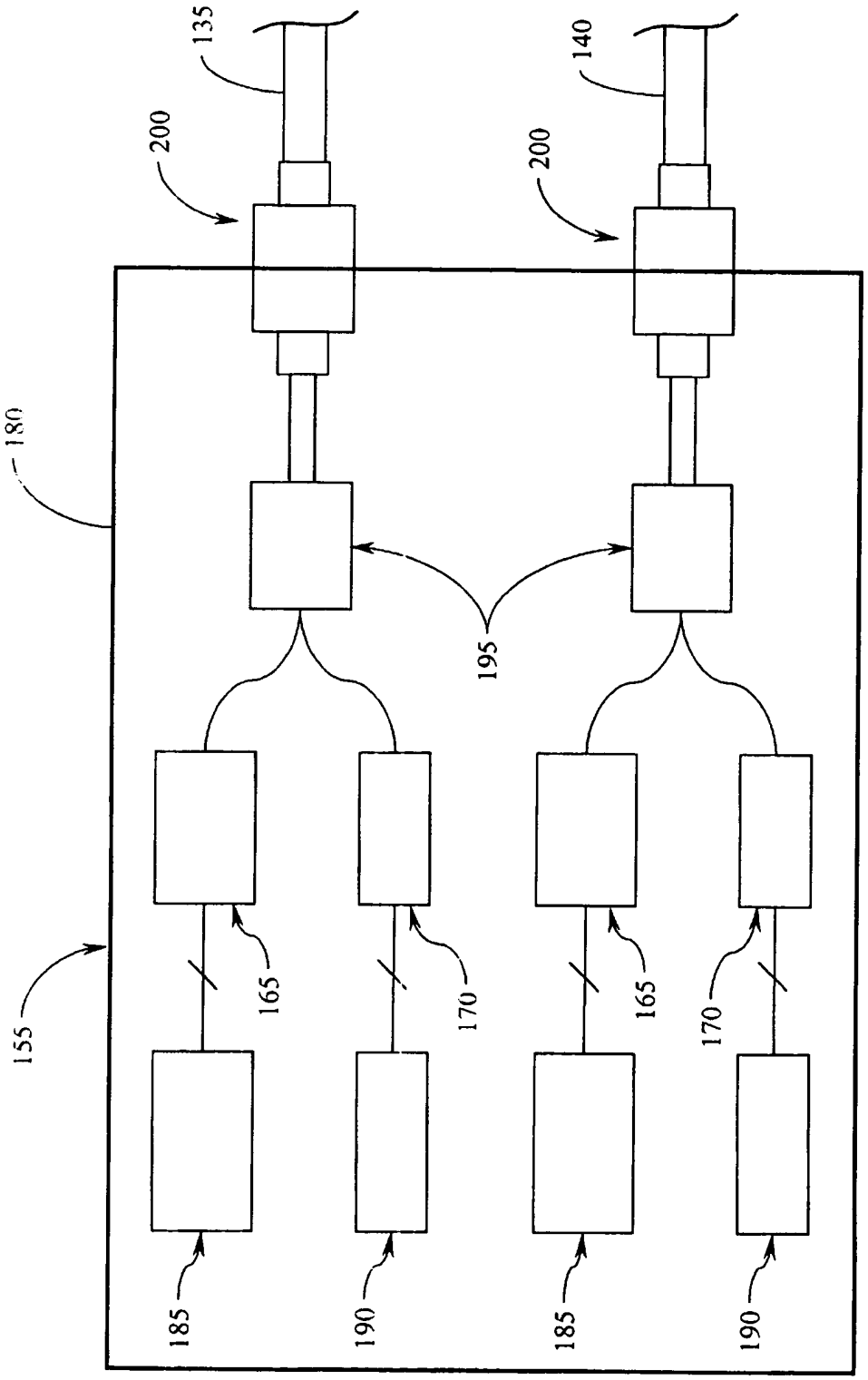

FIG. 4

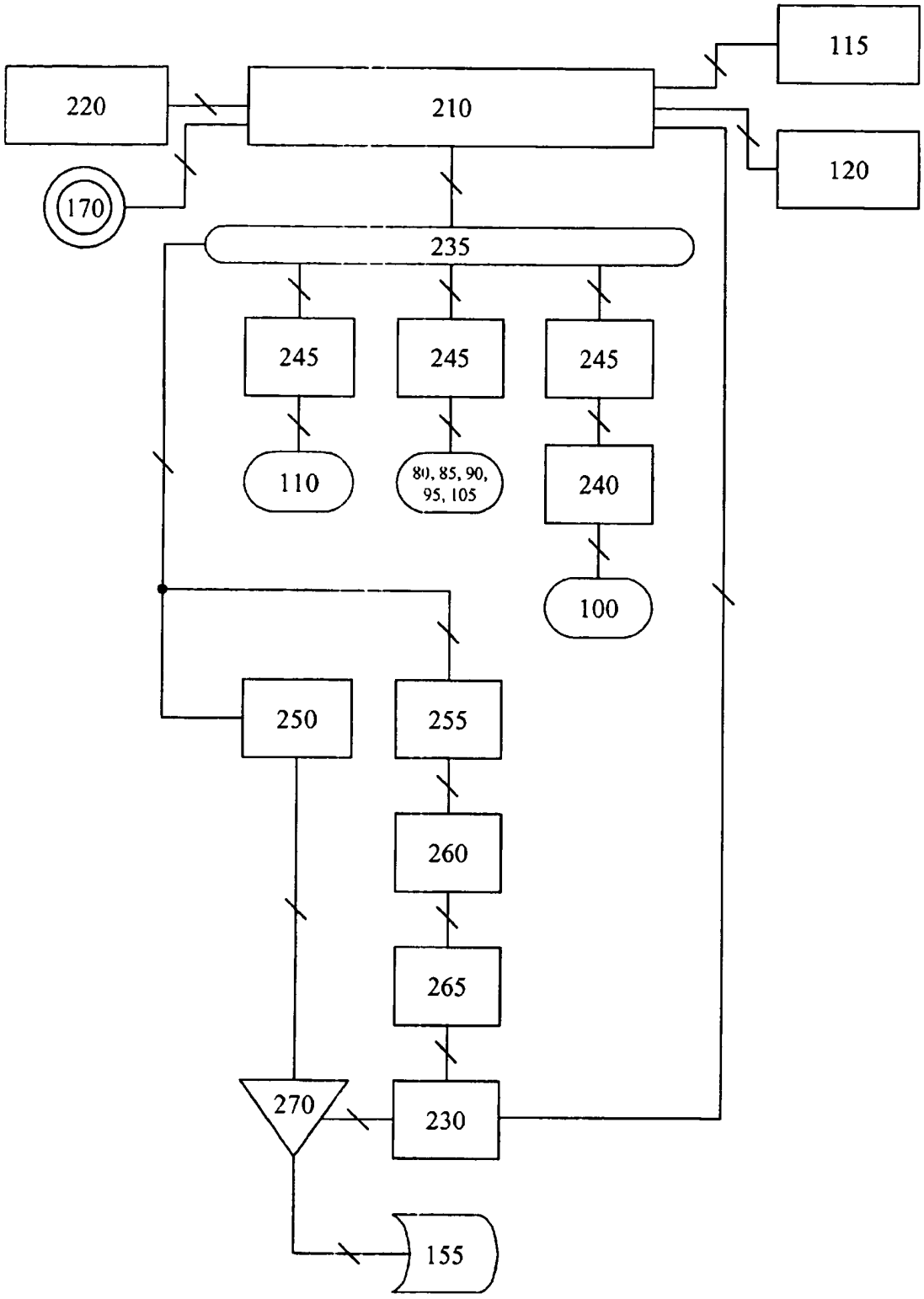
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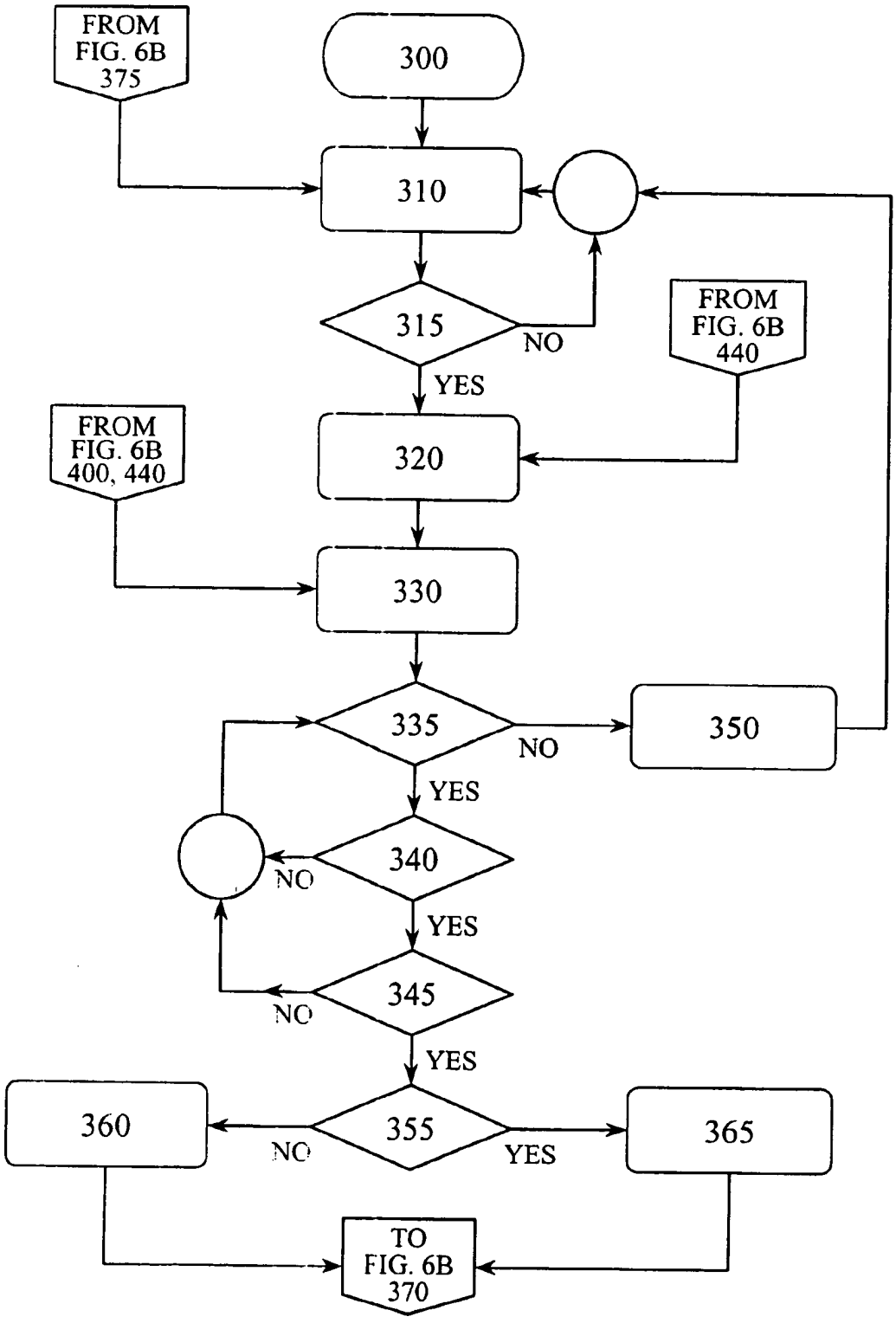
FIG. 5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FROM FIG. 6B 440
FROM FIG. 6B 400, 440
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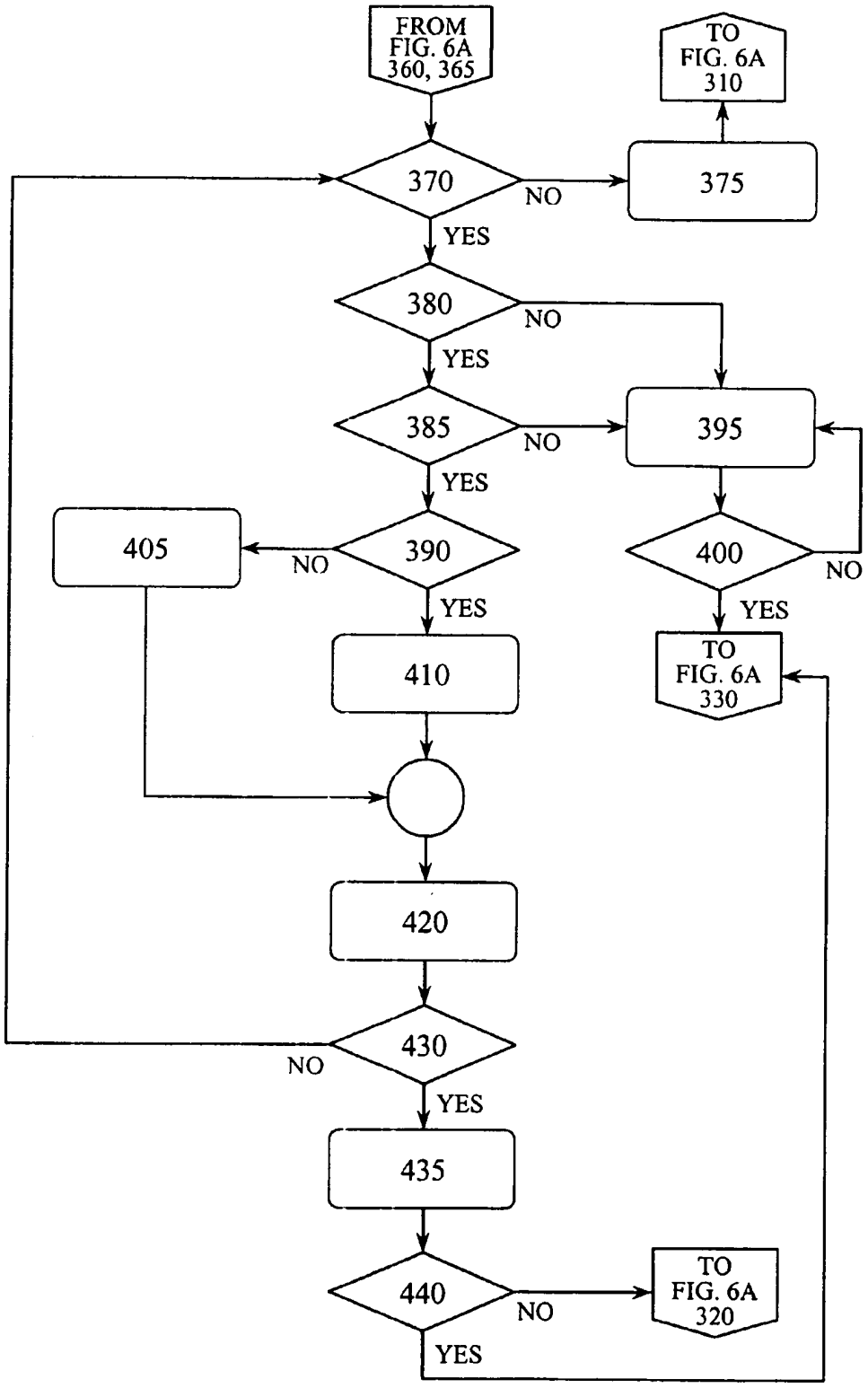
340
NO
YES
345
NO
YES
360
355
NO
YES
365
TO FIG. 6B 370

FIG. 6A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TO FIG. 6A 330
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430
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YES
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NO
TO FIG. 6A 320
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FIG. 6B

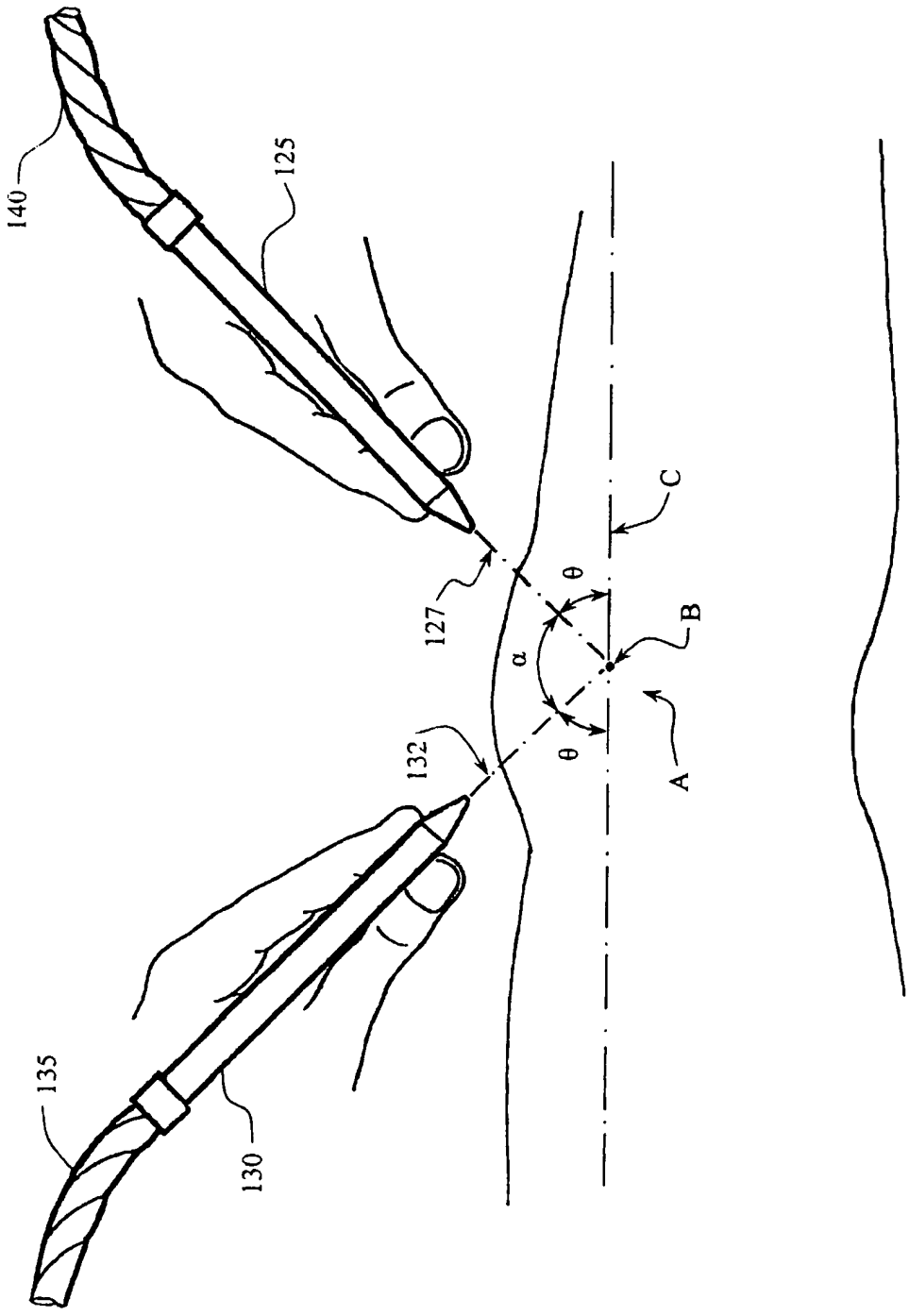

FIG. 7

METHOD AND APPARATUS FOR THERAPEUTIC LASER TREATMENT

TECHNICAL FIELD

The invention is directed to an apparatus and a method for applying laser beam energy in the treatment of medical conditions. More specifically, the present invention is concerned with an apparatus that uses wands emitting visible laser beam energy and invisible infrared laser beam energy. The method of the invention comprises positioning the wands over the patient in a manner such that the infrared radiation from the wands intersects within the body of the animal being subjected to therapy.

BACKGROUND OF THE INVENTION

The application of laser beam energy in the treatment of medical conditions has been investigated since the early 1970's. Numerous investigators have demonstrated that the application of low power laser beam energy on the order of 1 to 100 milliwatts and at varying wave lengths (e.g., 700–1100 nanometers) ("nm") is effective in the treatment of various medical conditions. Low-level laser beam energy has been shown to enhance wound healing and reduce the development of scar tissue after surgical procedures. Such energy has also been shown to relieve stiff joints and promote the healing of injured joints, stimulate the body's ability to heal fractures and large contusions, as well as enhancing the healing of decubitus ulcers.

Medical and dental applications for low level laser beam energy of varying wave lengths also include pain control, nerve stimulation, reduction of edema, reduction of inflammation, arthritis, muscle and tendon injuries, and stimulation of the body's neurohormone system. Other applications have demonstrated increased activity in cells specifically connected with the immune system and antigen response.

The mechanisms of how the tissues of a mammal respond to low power laser beam energy is not well elucidated or understood. Therapeutic laser treatments of humans, animals, and biological tissues have been commonly referred to as "photobiostimulation" treatments. Suggestions have been made that the process of photobiostimulation accelerates the initial phase of wound healing by altering the levels of prostaglandins. It has also been suggested the laser beam energy increases ATP synthesis, accelerates collagen synthesis, and increases the ability of immune cells to ward off invading pathogens. See, e.g., Bolognami et al., "Effects of GaAs Pulsed Lasers on ATP Concentration and ATPase Activity In Vitro and In Vivo," *International Cong. On Lasers in Medicine and Surgery*, p. 47 (1985); Karu and Letokhov, "Biological Action of Low-Intensity Monochromatic Light in the Visible Range," *Laser Photobiology and Photomedicine*, ed. Martellucci, pp. 57–66 (Plenum Press 1985); Passarella et al., "Certain Aspects of Helium-Neon Laser Irradiation on Biological Systems in Vitro," Ibid at pp. 67–74.

Conventional low power (less than 100 milliwatts) laser therapeutic devices generally comprise a hand held probe with a single laser beam source, or a large stationary table console with attached probes powered by a conventional fixed power supply. A common laser beam source is the laser diode. Laser diodes are readily available in varying power and wavelength combinations. Large probes containing multiple laser diodes are also known.

BACKGROUND ART

Isakov et al., in U.S. Pat. No. 4,069,823, disclose an apparatus for laser therapy including one or several lasers, a light guide and a focusing barrel wherein there are at least two platforms for transverse and longitudinal travel so that tissue can be dissected. The patent also discloses the use of a visible light beam that coincides with the laser beam thus allowing the surgeon to accurately aim the invisible laser beam to the required point. CO_2 lasers with wavelengths in the area of 1060 nm are employed. This patent also suggests laser beam densities of up to 10^5 watts per square centimeter.

Kanazawa et al. disclose in U.S. Pat. No. 4,640,283, a method of curing athlete's foot by laser beam irradiation. This patent discloses the use of a laser such as a CO_2 laser or a YAG laser that emits a laser beam in the infrared region having a wavelength of 700 nm or more. Energy levels are disclosed as two joules per centimeter squared or more for a period of ten milliseconds or less. This patent does not suggest or disclose the use of an apparatus including at least two wands for the laser therapy of medical conditions such as arthritis and bursitis.

Muchel in U.S. Pat. No. 4,699,839 discloses an optical system for therapeutic use of laser light. The Muchel instrument provides for combined observation of and laser treatment of a portion of a human body, such as an eye. This patent discloses the construction of main objective lenses within certain parameters adapted to combine laser therapy radiation from multiple sources. One source emits radiation having a wavelength of, for example, 1064 nm. A second source emits laser target light radiation having a wavelength of 633 nm. And a third source emits an observation light in the visible spectrum range of from 480 nm to 644 nm.

U.S. Pat. No. 4,671,285 to Walker discloses the treatment of human neurological problems by laser photo simulation. This patent relates to a method of treating nerve damage in humans by applying an essentially monochromic light to the skin area adjacent to the damaged nerve region. The inventor describes the use of a helium neon laser (632.5 nm, 1 milliwatt, and 20 hertz) with a fiber optic probe, which is held against the skin of the patient. The inventor also states that irradiation with infrared lasers (1090 nm) had no effect. This reference actually teaches away from the present invention.

Liss et al. teach in U.S. Pat. No. 4,724,835 a therapeutic laser device using a pulsed laser wave. The Liss et al. device uses a gallium aluminum arsenide diode as the source of laser energy which is in the infrared band (wavelength of approximately 900 nm).

U.S. Pat. No. 4,396,285 to Presta et al. relates to a laser system for medical applications that has at least two lasers and a movable concave reflector. One of the beams, an imaging beam, is aligned to impinge the reflector, to reflect therefrom and to impinge on a biological specimen. The reflector is moved until the beam is aligned to impinge the desired location of the specimens. The second beam is also aligned to impinge on the reflector to reflect therefrom and to impinge on the same desired position as that impinged upon by the first beam. The second laser is typically disclosed to be a CO_2 laser that generates the second beam having a wavelength of 10.6 microns. The Presta system is disclosed as being useful for microsurgery. This reference does not disclose a laser therapy apparatus wherein the therapeutic radiation and the targeting radiation are merged so as to be coincidental on the surface of the patient's skin and at least two wands for positioning the intersection of the beams within the body of the patient.

U.S. Pat. No. 4,930,504 to Diamantopoulos et al. relates to a device for biostimulation of tissue which comprises an array of monochromic radiation sources of a plurality of

wavelengths, preferably at least three different wavelengths. For example, this patent discloses the treatment of patients with a multi-diode biostimulation device having emitted frequencies of 660 nm, 820 nm, 880 nm, and 950 nm. The power levels disclosed are between 5 milliwatts and 500 milliwatts. This patent also discloses obtaining the radiation from a plurality of sources whose outputs are combined to a single emergence region with flexible optic fibers.

Labbé et al., in U.S. Pat. No. 5,021,452, disclose a process for improving wound healing which comprises administering ascorbate or derivatives of ascorbate to the wound site and then irradiating the wound site with a low power laser at a wavelength of about 600 nm to about 1100 nm. This patent discloses that the laser can either be a pulsed or a continuous wave laser with energy outputs ranging from 1.0 millijoule per square centimeter to about 1000 millijoules per square centimeter. This reference does not suggest or disclose an apparatus including at least two wands with a combined beam of therapeutic radiation and targeting radiation which are used to intersect the therapeutic radiation beams within the body of the animal subject to treatment.

U.S. Pat. No. 5,147,349 to Johnson et al. discloses a diode laser device for photocoagulation of the retina. The inventors disclose that the elliptical laser beam is shaped into a circle by an optical system before it is coupled to the fiber optic cable of the delivery system.

Mendes et al. in U.S. Pat. No. 5,259,380, discloses a light therapy system utilizing an array of light emitting diodes which emit non-coherent light in a narrow band width centered at a designated wavelength. The non-coherent light is generated by an array of conventional light emitting diodes with wavelengths in the red or infrared bandwidth. Infrared frequencies in the area of 940 nm, more particularly 880 nm are disclosed.

U.S. Pat. No. 5,409,482 to Diamantopoulos discloses a probe for biomodulation. The probe includes a semiconductor laser and a drive circuit adapted to operate the laser to emit pulses and bursts. The system according to this patent has a laser beam wavelength of 850 nm and a frequency of 352×10^3 GHz pulsed at 300,000 and additionally modulated at a frequency of from 1 Hz to 2 GHz.

Bellinger in U.S. Pat. No. 5,445,146 describes a laser system for the stimulation of biological tissue that emits radiation with a power of from 100 to 800 milliwatts in either a pulsed or continuous mode. The laser disclosed has a fundamental wavelength of **1064** nm and delivers an energy density of from about one joule per square centimeter to about 15 joules per square centimeter.

Smith in U.S. Pat. No. 5,464,436 discloses a laser therapy apparatus having a wavelength in the range of 800 to 870 nm and more preferably about 830 nm. The laser light is delivered to the afflicted area at a level of about one joule per square centimeter. Smith also suggests that the afflicted area be monitored after the treatment cycle and that treatment steps be repeated to the afflicted area.

U.S. Pat. No. 5,527,350 to Grove et al. discloses a method for treating psoriasis through the use of pulsed infrared laser irradiation. An infrared diode laser is used having a wavelength of 800 nm and a pulse duration in the millisecond range. Energy levels of 5.0 to 50 joules per square centimeter are disclosed.

U.S. Pat. No. 5,616,140 to Prescott discloses a portable laser bandage having one or many lasers or hyper-red light emitting diodes embedded in the bandage. The hyper-red light emitting diodes are disclosed as having wavelengths of about 670 nm.

PCT Application PCT/US93/04123 (WO 93/21993) discloses a low level laser for soft tissue treatment wherein the laser is a Nd:YAG laser, which produces 100 to 800 milliwatts in a pulsed or continuous mode.

In an article entitled;: "Low-Intensity Laser Reduces Arthritis Symptoms" by Pfieiffer in the *Journal of Clinical Laser Medicine & Surgery*, Vol. 10, No. 6, (1992), the author reviews various clinical studies using infrared and red lasers in the treatment of arthritis. This publication makes no disclosure of any specific laser therapy apparatus.

In a research report by Beckerman et al. entitled: "The Efficacy of Laser Therapy for Musculoskeletal and Skin Disorders: A Criteria-Based Meta-analysis of Randomized Clinical Trials", *Physical Therapy*, Vol. 72, No. 7, July, 1992, the authors review the results of 36 randomized clinical trials involving laser therapy. The article concludes that laser therapy seems to have a substantial, specific therapeutic effect. The authors also point out that it is difficult to determine the optimal dosage and treatment schedules. Further, the authors state that the minimal effective dosage in most cases is unknown and that additional questions need to be resolved regarding the optimal wavelength.

While a substantial amount of prior art exists regarding the use of laser therapies in medical conditions, no one has described or suggested an apparatus that comprises at least two wands that emit coincident visible and infrared radiation, wherein the infrared radiation has a wavelength of about 1000 nm. Further, none of the prior investigators have suggested aiming the at least two wands on the surface of the animal being treated so as to have the therapeutic infrared radiation beams intersect inside the animal's body at the site of therapy.

SUMMARY OF THE INVENTION

The therapeutic laser apparatus according to the invention has at least two independent fiber optic laser outputs terminating with wands that have apertures with variable foci. The inventive apparatus also has a main function block wherein the therapeutic infrared radiation is combined with visible laser light and fed into fiber optic cables via couplers. The fiber optic cables transmit the radiation to the wands. The main function block also contains at least two infrared diode lasers and at least two red diode lasers. Through the design of at least two wands, a novel method of therapy has been discovered wherein the patient or caregiver positions the wands in such a manner that the infrared radiation (at about 1000 nm) from the wands intersects at the point of therapy (inside the body), thereby relieving pain and promoting regeneration of tissue.

The amount of energy applied by each wand can range from about 200 to about 2,000 milliwatts. Preferably, the wands are held in each hand of the caregiver at an angle of about 45° relative to the plane of the patient or biological tissue undergoing treatment. The wands are slowly moved in small circular motions favoring positions that allow the beams of laser radiation to intersect in the body at the site of the malady. As will be disclosed below, the apparatus according to the invention can be effectively used to treat joints affected by arthritis and sore muscles. Patients with advanced forms of degenerative arthritis have experienced pain relief and, over time, revitalization of joints previously affected by the disease.

The concept of using heat (infrared radiation) for relief from pain has been practiced for thousands of years. Electrically heated pads have found wide spread use for pain

relief on all parts of the human body and this application of infrared radiation for pain relief is usually referred to as diathermy. It has been discovered that the treatment of a patient with a device according to this invention is not simply receiving heat treatment or diathermy. The actual body mechanisms responsible for relief from pain and revitalization of joints and other tissue are not completely understood. The inventors have observed that the treatments with this particular wavelength of about 1,000 nm and the delivery mechanism of at least two wands is especially effective in the treatment of arthritis.

In the main function block, two infrared diode lasers and two red diode lasers are preferably coupled so that these two frequencies are transmitted to the wands via the fiber optic cable. The combined infrared laser radiation and the visible laser light exit the treatment aperture in the wand coincident and therefore provide an excellent aiming mechanism to the caregiver or patient.

The diameter of the fibers used in the apparatus according to the invention may vary over a wide range. However, the diameter is preferably between approximately 400 microns and approximately 800 microns, and more preferably approximately 600 microns, and even more preferably approximately 400 microns. The preferred wavelength of the infrared lasers is between approximately 900 nm and approximately 1100 nm with the best results being obtained with a wavelength of about 980 nm. The low power visible aiming laser component is typically a red diode laser having a wavelength of between about 400 nm and about 700 nm, and more preferably between about 635 nm and about 640 nm. The wavelength of approximately 635–640 nm is preferred because of its high visibility and minimized effect on the human eye. The power output per wand can range from about 0.0001 milliwatts watts to about 2.0 watts.

Thus, there is disclosed a device for biostimulation of biological tissue that includes

a) at least two radiation sources providing a first wavelength of between approximately 900 nm to approximately 1100 nm;

b) at least two radiation sources providing a second wavelength of between approximately 400 nm to approximately 700 nm; the radiation sources being arranged such that the first and second wavelengths simultaneously pass through a fiber optic cable;

c) at least two wands connected to the fiber optic cable and having apertures having variable focus; the wands being arranged such that the coincident first wavelength and second wavelength emitted from each wand pass through a region located within the tissue.

There is further disclosed a method for the treatment of tissue including:

a) providing at least two infrared laser radiation sources having a wavelength of between approximately 900 nm to approximately 1100 nm;

b) providing at least two sources of laser radiation having a wavelength between approximately 400 nm and 700 nm;

c) combining the radiation sources so that the radiation of each source is coincident;

d) passing the coincident radiation through an optical fiber;

e) providing at least two wands connected to the optical fiber;

f) arranging the wands such that the radiation emitted from each of the wands passes through a region located within the tissue; and

g) exposing the tissue to an irradiation beam for a therapeutically effective period of time.

Also disclosed is a device for photobiostimulation of biological tissue that includes:

a) a first plurality of treatment radiation sources each providing a respective first radiation beam having a wavelength of between approximately 900 nm and approximately 1100 nm;

b) a second plurality of aiming radiation sources each providing a respective second radiation beam having a wavelength of between approximately 400 nm and approximately 700 nm; wherein at least one first beam and one second beam concurrently pass through at least one of a plurality of fiber optic cables; and

c) at least two wands each connected to a different one of the plurality of fiber optic cables, the wands including a collimator configured to establish the focus of the emanating coincident radiation beams; wherein the wands are arranged in an operative position about the tissue such that the radiation beams emitted from each wand simultaneously pass approximately through a region located in the tissue.

The invention also contemplates and discloses a biostimulation device that includes a laser apparatus including a plurality of treatment laser wands each connected to a laser radiation source adapted to emit radiation having a power of between zero and approximately 2.0 watts, an energy of between about 1 joules and about 99 joules, and a wavelength of between approximately 900 nm and 1100 nm; and wherein the laser wands are arranged in an operative position to emit the radiation incident to a region of biological tissue for a therapeutically effective length of time between approximately one and approximately sixty minutes.

Further, a system for photobiostimulation of biological tissue is disclosed. The system includes a controller unit including a power supply and a control panel having operator input devices and output devices;

the controller unit also including a first plurality of treatment radiation sources each providing a respective first radiation beam having a wavelength of between approximately 900 nm and approximately 1100 nm;

the controller unit also including a second plurality of aiming radiation sources each providing a respective second radiation beam having a wavelength of between approximately 400 nm and approximately 700 nm; wherein at least one first radiation beam and one second radiation beam concurrently pass through at least one of a plurality of fiber optic cables; and

at least two wands each connected to a different one of the plurality of fiber optic cables, the wands including a collimator configured to establish the shape of the emanating coincident radiation beams; wherein the wands are arranged in an operative position about the tissue such that the radiation beams emitted from each wand simultaneously pass approximately through a region located in the tissue.

The apparatus according to the invention further includes a controller, a control panel, a power source, and components configured to vary the radiation power and energy, pulse frequency, pulse duration, and duration of the biostimulation treatment.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a perspective view, in reduced scale, of a biostimulation device incorporating a therapeutic laser apparatus of the present invention;

FIG. 2 is a diagrammatic representation of the operation panel of the therapeutic laser apparatus of FIG. 1;

FIG. 3 is a cross-sectional view, in enlarged scale, of the laser wands of FIG. 1;

FIG. 4 is a schematic functional representation of the laser radiation sources of the therapeutic laser apparatus of FIG. 1;

FIG. 5 is a schematic functional representation of the major sub-components of the therapeutic laser apparatus of FIG. 1;

FIGS. 6A and 6B are functional descriptions of the method of operation of the therapeutic laser apparatus of the present invention; and

FIG. 7 is a side view of an embodiment of the laser wands of the apparatus of FIGS. 1 and 2, in enlarged scale, in operation and directed towards a human knee undergoing therapeutic biostimulation.

DETAILED DESCRIPTION OF THE INVENTION

The sources of radiation are preferably semiconductor laser diodes, super-luminous diodes, or light emitting devices, and more preferably are solid-state laser diodes (SSDs). Laser diodes or SSDs produce a beam of light or radiation that is essentially monochromatic, sharply collimated, and coherent. That is, they produce light almost exclusively at one frequency and the light beam has a small angle of divergence. A number of commercially available semiconductor laser diodes exist that are suitable for purposes of the present invention.

Referring now to FIG. 1, the preferred embodiment of the present invention is a device **10** for biostimulation of biological tissue that includes a controller cabinet **20** that houses various subcomponents. The cabinet **20** may be mounted to a roller pedestal **30** and it is, in one embodiment, connected to an operator safety pedal **40** and a plurality of laser treatment wands **50** that may be received into a laser radiation shielding receptacle **60**. For convenience, the receptacle **60** may be mounted to the cabinet **20**. The cabinet is formed with a control panel **70** that includes various input and output devices needed for operating the device **10**. Also, although not shown in the various figures, the invention contemplates a room entry-way safety interlock. The safety interlock connects a safety switch mounted to the door-way of the room that houses the therapeutic laser device to the device **10**. The safety switch is configured to de-energize all or some of the laser radiation sources upon opening of the door to the room. Inadvertent injury is prevented because laser radiation cannot escape the treatment room. In the preferred embodiment, the entry-way safety interlock is connected to the device **10** and may be portably mounted on any door-way so that the device **10** may be easily moved between a plurality of treatment rooms. Additionally, although pedal **40** is shown in the various figures, the pedal **40** may be accompanied by or entirely replaced by a safety switch mounted on either or both of the laser treatment wands described below.

With continued reference to FIG. 1 and also FIG. 2, it can be understood that the control panel **70** further includes a master power switch **80**, an emergency stop switch **85**, and an operator's safety arming key switch **90**. If the arming key is removed from the switch **90**, power to laser radiation sources of the device **10** is interrupted to prevent operation of the lasers. Also included on the control panel is a mode switch **95** configured to operate the device **10** in either single or dual laser mode. A numeric entry keypad **100** similar in design to a typical telephone keypad is mounted on the control for configuring the various operating parameters of the device **10** as described in more detail below. The keypad **100** is preferably a hermetically sealed, membrane keypad. A resume switch **105** is also included that is operative to continue interrupted operation.

An output display group on the control panel **70** includes various component status indicators. The indicators include, for example, light emitting diodes (LEDs) **110**, liquid crystal alphanumeric displays (LCDs) **115**, **120**, and audio emitting event buzzers, not shown, each operative to signal component and system status, to prompt the operator for needed input, and to warn of system anomalies and malfunctions. The LCDs are, for example, back-lit, 4 linex20 character displays. The indicators can also indicate the status of the foot pedal **40** and whether any access panels or doors of the main cabinet **20** are open. All access panels or doors of the main cabinet **20** incorporate interlock sensors operative to disconnect power to the laser radiation sources or the device **10**, or both, for safety. Additional LEDs **110** and LCDs **115**, **120** may also be incorporated to signal that the treatment room door is open or ajar.

Each of the treatment wands **125**, **130** of the plurality **50** is connected via fiber optic cables **135**, **140** to radiation sources, not shown, inside the cabinet **20**. The preferred fiber optic cable for use with the present invention is approximately a **400** micron fiber. Referring now to FIG. 3, it will be observed that each treatment wand **125**, **130** incorporates a collimator lens **145** operative to focus the treatment laser beam emitted from the fiber optic cables **135**, **140** into the desired beam shape and to project the beam outwardly. In one embodiment of the present invention, the wands each also include an adjustable collimator holder **150** that can be adjusted to vary the shape and focus of the emitted beam. An example of the preferred collimator **145** is an aspheric collimator lens having a focal length of approximately 6.25 millimeters. Typical laser radiation energy losses at each surface of the collimator **145** are, on average, about 4 percent. Therefore, each lens surface **146**, **147** preferably includes an anti-reflection coating adapted to minimize the losses at each surface to approximately 0.5 percent. Additionally, the collimator **145** and the holder **150** are arranged to preferably emit a generally circular beam spot having an approximately 4 millimeter diameter. The wands are preferably about 5 to 6 inches in length and are made of aluminum. However, they can be made from any suitable material including, for example, metal, plastic, ceramic, glass, and combinations thereof

With reference to FIG. 4, each treatment wand **125**, **130** emits laser radiation energy transmitted from at least one of a plurality of laser radiation sources **155** that are preferably contained in a single unit, heat sinked assembly **180**. In the preferred embodiment, the laser radiation sources are selected to emit infrared or visible laser radiation, or both. In the preferred embodiment, infrared treatment laser radiation from one source **165** of the plurality **155** is combined with visible laser radiation from another source **170** of the plurality **155** and transmitted into at least one of the fiber optic cables **135**, **140**.

In this configuration, the positioning of the invisible infrared laser radiation is emitted coincident with the visible laser radiation so that the operator can properly aim the infrared laser radiation emitted from each wand **125**, **130** during therapy. Laser radiation sources suitable for use with the present invention include a high-power, Class 4, infrared wavelength SSD laser and a Class 1 or 2, visible wavelength SSD laser available from B. & W. Tek, Inc. of Newark, Del.

U.S.A. Each of these sources is combined into the single unit assembly **180**. In the preferred embodiment of the invention, the assembly **180** incorporates a power supply **185, 190** for each laser radiation source **165,170**. Also, available from B. & W. Tek is a combiner **195** configured to combine the invisible and visible laser radiation energy into a single fiber optic cable **135, 140** via a releasable, SMA **906** compliant, fiber optic coupler **200**.

Each of the infrared treatment laser radiation sources **165** is adapted to emit Class 4 infrared treatment laser radiation with an adjustable power of preferably between approximately zero and approximately 10.0 watts, and more preferably between approximately zero and approximately 5.0 watts, and even more preferably between approximately zero and approximately 2.0 watts. This capability assures an emitted infrared treatment laser radiation power at the treatment end of each of the wands **125, 130** of preferably between about zero and approximately 2.0 watts. These parameters account for many variables including the ability of the biological tissue to absorb radiation and the unavoidable power losses in the combiner **195**, coupler **200**, cables **135, 140**, and wands **125, 130**. Additionally, each of the infrared treatment laser radiation sources **165** are further configured to emit laser radiation having a wavelength preferably between approximately 900 nanometers ("nm") and approximately 1100 nm, and more preferably approximately 980 nm.

Each of the visible laser radiation sources **170** are preferably configured to emit Class 1 to Class 2 laser radiation with either a fixed or adjustable power of approximately 0.5 milliwatts to approximately 6 milliwatts. This capability assures a visible emitted laser radiation power at the treatment end of each of the wands **125, 130** including the unavoidable power losses in the combiner **195**, coupler **200**, cable **135, 140**, and wands **125, 130**. Additionally, each of the visible laser radiation sources **170** is also configured to emit radiation having a wavelength preferably between approximately 400 nm to approximately 700 nm, and more preferably between about 635 nm and about 640 nm.

Although only four laser radiation sources **165, 170** are described above and shown in FIG. **4**, the plurality **155** contemplates any number of greater and fewer laser sources configured to emit laser radiation at various power levels and wavelengths for one or more wands or therapeutic treatment applicators or emitters. Additionally, although a circular beam shape of approximately 4 mm is disclosed, a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patterns are also suitable for use with the present invention. Such patterns also include rectangular, square, oval, and elliptical patterns, as well as predetermined or random movably scanned or traced beam patterns that are adapted to be spread over a selected region or to trace a specific shape or pattern.

With reference to FIG. **1** and the block-diagram schematic represented in FIG. **5**, the cabinet **20** incorporates various components interconnected with the control panel **70**, the laser radiation sources **155** and wands **125, 130**, and the foot pedal **40**. The components are configured to control the laser radiation sources **165, 170** for therapeutically effective biostimulation of human, animal, and experimental biological tissues. The device **10** includes a single board computer or controller component **210** that is preprogrammed to control each of the other components and functions of the device **10**. One example of a suitable controller **210** is the BASIC Stamp II-SX microcontroller and accompanying chip set from Parallax, Inc., of Rocklin, Calif. The controller **210** electronically communicates with a year 2000 compliant clock such as the Pocket Watch B 220 from Solutions[3] (Solutions Cubed) of Chico, Calif., the audio emitter **170**, and the LCDs **115, 120**. The controller **210** communicates directly with the laser radiation sources **155** through both a multiplexer interface circuit **230** and an information bus interface circuit **235** such as, for example, the I^2C serial bus chip set available from Philips Semiconductors of Sunnyvale, Calif. The keypad **100** electronically communicates with the controller **210** via the bus **235** through a decoder circuit **240** and an 8-bit, quasi-bidirectional expander **245**. The indicators **110** and the switches **80, 85, 90, 95, 105** also communicate with the controller **210** via the bus **235** through converters **245**. An example of a decoder circuit or chip set **240** suitable for use in the present invention is the model 74HC147 chip available from Harris Semiconductor, Inc. of Palm Bay, Fla. An example of a suitable 8-bit, quasi-bidirectional expander circuit or chip set **245** is the model PCF8574 I^2C bus compatible chip set available from Philips Semiconductors.

The controller **210** also communicates with and controls the power, duration, pulse frequency, and pulse width or duty cycle of the laser radiation sources **155** through the bus **235**, and through various interface circuits. The primary interface circuit stage includes dual, independently operable 8-bit digital-to-analog converters **250, 255**. The first converter **250** is configured to provide a controlled output voltage of between approximately zero volts and approximately 1.25 volts and is adapted to drive the power output of the laser sources **155**. The second converter **255** is configured to provide a controlled output of between approximately zero volts and 5 volts and is adapted to drive a laser pulse frequency and duty cycle interface circuit. One example of an adequate converter **250, 255** is the model PCF8591 I^2C bus compatible converter also available from Phillips Semiconductors.

The converter **255** drives a voltage controlled oscillator ("VCO") **260** configured to output a signal modulated between approximately 100 Hertz ("Hz") and 1,000 Hz. A suitable VCO **260** is the model AD654 VCO available from Analog Devices, Inc. of Norwood, Mass. The VCO **260** electronically communicates with a pulse width modulator ("PWM") circuit or chipset **265** that can be obtained as the model PALCE610 PWM available from Vantis Semiconductor, Inc. (formerly Altera Corporation) of San Jose, Calif. The PWM **265** also communicates with the multiplexer **230**, through the laser driver interface **270**, and with the laser radiation sources **155**.

The controller **210** is programmed to accept operator input from the keypad **100** and the mode switch **95** in response to prompting displayed on the LCDs **115, 120** to obtain the desired power wattage and joule energy levels of the treatment laser radiation sources **165**, and to determine whether continuous wave or pulsed wave operation is needed for the desired therapeutic treatment. The controller **210** then computes the duration of time required for application of the therapeutic laser treatment. To accomplish this computation, the controller **210** is programmed, among other aspects, with a power to energy conversion equation that computes time in seconds as a function equal to energy in joules divided by power in watts (T=ExP). If the operator selects pulsed wave operation, the controller **210** prompts for the desired frequency and pulse width or duty cycle. As an example, the operator may select a frequency of one hertz (cycles per second) and a pulse width of 50%. In the preferred embodiment, the pulse width is adjustable between approximately 0.1% and 100%. The controller **210** would then set the laser radiation source or sources to have a pulse

frequency of one cycle per second wherein the radiation pulse or pulses are on for 0.5 seconds and off for 0.5 seconds. The controller **210** may also be programmed to adjust the power wattage levels and joule energy levels, as well as the continuous wave or pulsed wave operation of each of the laser radiation sources synchronously or independently. Continuous wave operation is selected by specifying a pulse width or duty cycle of 100%. As an additional safety feature, the controller **210** may be programmed to limit the maximum time of treatment to, for example, 60 minutes. Additionally, the operator may similarly adjust the power level or "brightness" of the visible laser radiation source(s) and to select a pulsed or continuous wave operation.

The controller **255** also preferably electronically communicates with a hardware reset switch and a serial port interface circuit, not shown, but incorporated into the back plane of the cabinet **20**. The hardware-reset switch is preferably operative to perform a low-level system reset in the event of hardware or software anomalies in device **10**. The serial port is configured to communicate with the controller **210** for purposes of external software control of the device **10** or its components, e.g., the lasers, or both. Also, the serial port can be configured to allow remote monitoring of device diagnostics, and to upload software upgrades to the device **10**.

Referring now to FIGS. **1**, **6A**, and **6B**, the device **10** is operated by first energizing the power switch **80** on the control panel **70**. The preprogrammed logic of the controller **210** initiates a system self-test subroutine **300** and displays progress, system status, and operator welcome messages **310** on the LCDs **115**, **120**. The logic programmed into the controller **210** next scans the status **315** of the arming key switch **90**. An operator's key must be inserted into the arming switch **90** before any of the laser radiation sources **165**, **170** can be energized.

The controller continuously scans the arming switch **90** and automatically detects when the switch has been energized. Once energized, the controller **210** next executes a user prompt routine **320** that displays operator prompts on the LCDs **115**, **120** requesting the desired parameter settings for the energy dosage in joules, power setting in watts per wand, pulse frequency (if any), and pulse width or duty cycle. After the desired parameters have been entered via the keypad **100**, the controller **210** continues to execute routine **320** to compute the time required to accomplish the procedure according to the entered parameters. After the time computation is completed, routine **330** executes to energize the visible light and aiming laser radiation sources **170**. At this point, the laser wands **125**, **130** can be aimed because the visible wavelength laser beams are emitted from the wands. If the mode switch **95** has been adjusted to select single laser operation, then only one of the aiming laser radiation sources **170** will be energized. In alternative embodiments, although not shown in the figures, either an analog switch or a keypad **100** entry can be made to adjust the intensity of the aiming laser radiation sources **170**, if needed.

After the aiming laser radiation sources **170** have been energized, routine **335** is executed to ensure the key switch **90** remains energized, routine **340** is executed to ensure that all access doors are closed, and routine **345** is executed to make sure the foot pedal **40** is depressed. If all safety checks do not pass, then control is returned to routine **335**. If the key switch **90** is no longer energized, then the aiming laser radiation sources are de-energized by routine **350** and control passes back to the welcome message prompt routine **310**. Also, although not reflected in the various figures, opening of the treatment room entry door during treatment also executes routine **350**. However, if all safety checks pass, then routine **355** executes to check the mode switch **95**. If single laser or dual laser operation is selected, then either routine **360** or **365**, respectively, is executed to energize either one or both therapeutic laser radiation sources **165**. If additional laser radiation sources are available, then the mode switch would be adjusted to establish which of the plurality of laser radiation sources were to be energized.

Once all of the selected lasers have been energized, routine **370** executes to check the key switch **90**. If de-energized, control passes to routine **375** to de-energize all of the lasers **165**, **170** and control passes to the welcome message prompt routine **310**. Otherwise, routines **380**, **385**, and **390** execute to respectively check to ensure all access doors and panels remain closed, that the pedal **40** remains depressed, and to check if the mode switch **95** has been adjusted. If any of the cabinet doors or access panels have been opened, routine **395** executes to de-energize all of the laser radiation sources **165**, **170**. Although not reflected in the various figures, opening of the treatment room entry door during treatment also executes routine **395**. The operator is then prompted by "pause-resume" routine **400**, which executes and sends a message to either or both of the LCDs **115**, **120**, and, if desired, a signal to the audio emitter **170**. The operator may respond to the prompts and alerts by depressing the resume switch **105**, returning control to routine **330** to initiate the series of pre-energization safety checks. Similarly, if routine **385** determines that the foot pedal **40** is no longer depressed, control passes to the all lasers off routine **395** and then to the pause-resume routine **400**.

If all doors and panels have not been opened and remain closed and the foot pedal remains depressed, then mode switch check routine **390** executes to poll the mode switch **95**. If the switch **95** has been adjusted, then the second laser radiation source is accordingly energized by routine **405** or de-energized by routine **410**. Operation control then proceeds to counter routine **420** which increments the time remaining for the procedure as calculated initially by routine **320**. Control then passes to timer routine **430**. If the duration of time needed to complete the procedure has passed, then routine **435** executes to de-energize all laser radiation sources **165**, **170**. The operator is queried by routine **440**, which sends a signal to the audio emitter **170**, if desired, and displays prompts on the LCDs **115**, **120**, to determine whether the therapeutic laser application procedure should be repeated. If not, control passes to the operator prompt routine **320**. If the operator elects to repeat the procedure, then control is transferred to routine **330**, and the above operations are repeated.

The present invention also includes a method for treatment of tissue. The method involves exposing the tissue to a plurality of radiation sources having a wavelength of between approximately 900 nm and approximately 1100 nm. More generally, the method of treatment of the present invention involves the exposure of the tissue to a plurality of converging beams of infrared radiation of between about 900 nm and 1100 nm. Any embodiment of the device of the present invention, including but not limited to those previously described, can be used to perform this method of treatment.

Referring next to FIG. **7**, the operator hands are shown holding the laser wands **125**, **130** above the biological tissue "A" to be treated. As shown, the wands **125**, **130** are preferably positioned so the beams intersect at a region "B"

of the biological tissue "A" undergoing treatment. The wands **125, 130** are preferably oriented at an angle α (alpha) relative to each other and an angle θ (theta) to an imaginary, approximately horizontal reference line "C" passing through the tissue undergoing treatment so that the beams **127, 132** intersect. The intersection of the emitted infrared, treatment laser radiation significantly improves the absorption of the energy by the tissue at and proximate to the region or point of intersection "B" of the beams **127, 132**. The operator preselects the region or regions to be treated and may vary the location of the intersection region "B" by adjusting the position and orientation of the wands **125, 130**.

Obstacles to radiation penetration, such as oils or other substances on the surface of the skin, should be preferably removed before treatment because they may absorb, refract, and/or diffract the incident radiation, and thereby decrease radiation penetration. Because oils or other substances on the surface of the skin may cause absorption, fraction, reflection, and/or defraction of the wavelength of radiation, and thereby decrease radiation penetration, these obstacles should be removed before treatment.

Although not shown in the figures, the invention also contemplates an automatic positioning device configured to fixedly and/or changeably adjust the position and orientation of the wands **125, 130** relative to one another and relative to the biological tissue undergoing therapeutic laser treatment. The positioning device is configured to adjust position and orientation of the wands **125, 130** into an operative position with the emitted aiming and therapeutic laser beams having an intersection region within the biological tissue receiving the treatment similar to the description above and in FIG. **7**. The positioning device may include an assembly operative to automatically vary the relative positions and orientation of the wands **125, 130** during the therapeutic laser application.

From the foregoing, it would be obvious to those skilled in the art that various modifications in the above described method and apparatus can be made without departing from the spirit and scope of the invention. Accordingly, the invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. Present embodiments, therefore, are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced thereby.

What is claimed is:

1. A biostimulation device, comprising:

a) a laser apparatus including a plurality of variably focusable treatment laser wands each connected to (1) a first laser radiation source adapted to emit radiation having a power of between zero and approximately 2.0 watts, an energy of between about 1 joule and about 99 joules, and a wavelength of between approximately 900 nm and 1100 nm, and (2) a second radiation source adapted to emit visible light; and

b) wherein the laser wands are adapted to be arranged in an operative position to emit the radiation incident to a region of biological tissue for a therapeutically effective length of time between approximately one and approximately sixty minutes.

2. A biostimulation device, comprising:

a) a laser apparatus including a plurality of treatment laser wands each connected to a first laser radiation source adapted to emit radiation having a power of approximately between 1 and 10 watts, an energy of between about 1 joule and about 99 joules, and a wavelength of between approximately 900 nm and 1100 mn, and a second radiation source adapted to emit visible light; and

b) wherein the laser wands are focusable and adapted to be arranged in an operative position to emit the radiation incident to a region of biological tissue for a therapeutically effective length of time.

3. A device for photobiostimulation of biological tissue, comprising:

a) a first plurality of treatment radiation sources each providing a respective first radiation beam having a wavelength of between approximately 900 nm and approximately 1100 nm;

b) a second plurality of aiming radiation sources each providing a respective second radiation beam having a wavelength of between approximately 400 nm and approximately 700 nm; wherein at least one first beam and one second beam concurrently pass through at least one of a plurality of fiber optic cables; and

c) at least two wands each connected to a different one of the plurality of fiber optic cables, the wands including a variable collimator configured to establish the focus of the emanating coincident radiation beam;

wherein the wands are adapted to be arranged in an operative position about the tissue such that the radiation beams emitted from each wand simultaneously pass approximately through a region located in the tissue.

4. The biostimulation device of claim **3**, wherein the treatment and aiming radiation sources incorporate light emitting diode lasers.

5. The biostimulation device of claim **3**, wherein the treatment radiation source emits radiation having a wavelength of approximately 980 nm.

6. The biostimulation device of claim **3**, wherein the aiming radiation source emits radiation having a wavelength of between approximately 635 nm and approximately 640 nm.

7. The biostimulation device of claim **3**, wherein at least one of the wands incorporates an adjustable collimator operative to vary the focus of the emitted radiation beam.

8. The biostimulation device of claim **3**, wherein the treatment radiation source is configured to emit adjustably pulsed radiation wherein the pulses have a frequency of between approximately 0.1 cycles per second and approximately 100 cycles per second.

9. The biostimulation device of claim **3**, wherein the treatment radiation source is configured to emit continuous wave radiation.

10. The biostimulation device of claim **3**, wherein the treatment radiation source is configured to adjustably emit pulsed radiation wherein the pulse width is between approximately 0.1 percent and 100 percent.

11. The biostimulation device of claim **3**, wherein the treatment radiation source is configured to adjust the power level of the emitted radiation to have a power of between zero and approximately 2.0 watts.

12. The biostimulation device of claim **3**, wherein the treatment radiation source is configured to adjust the energy level of the emitted radiation to have a power of between approximately 1 joule and 99 joules.

13. The biostimulation device of claim **11** or **12**, wherein the treatment radiation source is configured to adjust the duration of the therapeutic laser radiation treatment to between approximately 1 second and 3600 seconds.

14. A method for the treatment of tissue, comprising the steps of:

a) providing at least two infrared laser treatment radiation sources having a wavelength of between approximately 900 nm and approximately 1100 nm;

b) providing at least two sources of aiming laser radiation having a wavelength of between approximately 400 nm and approximately 700 nm;

c) combining the radiation sources so that the radiation of each source is coincident;

d) passing the coincident radiation through at least two optical fibers;

e) providing at least two wands connected to the optical fibers that include a focusable collimator;

f) arranging the wands such that the radiation emitted from the wands simultaneously passes through a region located within the tissue; and

g) exposing the tissue to the laser radiation for a therapeutically effective period of time.

15. The method for the treatment of tissue of claim 14, wherein the treatment and aiming radiation sources incorporate light emitting diode lasers.

16. The method for the treatment of tissue of claim 14, wherein the treatment radiation source emits radiation having a wavelength of approximately 980 nm.

17. The method for the treatment of tissue of claim 14, wherein the aiming radiation source emits radiation having a wavelength of between approximately 635 nm and approximately 640 nm.

18. The method for the treatment of tissue of claim 14, wherein at least one of the wands incorporates an adjustable collimator operative to vary the focus of the emitted radiation beam.

19. The method for the treatment of tissue of claim 14, wherein the treatment radiation source is configured to emit adjustably pulsed radiation wherein the pulses have a frequency of between approximately 0.1 cycles per second and approximately 100 cycles per second.

20. The method for the treatment of tissue of claim 14, wherein the treatment radiation source is configured to emit continuous wave radiation.

21. The method for the treatment of tissue of claim 14, wherein the treatment radiation source is configured to adjustably emit pulsed radiation wherein the pulse width is between approximately 0.1 percent and 100 percent.

22. The method for the treatment of tissue of claim 14, wherein the treatment radiation source is configured to adjust the power level of the emitted radiation to have a power of between zero and approximately 2.0 watts.

23. The method for the treatment of tissue of claim 14, wherein the treatment radiation source is configured to adjust the energy level of the emitted radiation to have a power of between approximately 1 joule and 99 joules.

24. The method for the treatment of tissue of claim 22 or claim 23, wherein the treatment radiation source is configured to adjust the duration of the therapeutic laser radiation treatment to between approximately 1 second and 3600 seconds.

25. A system for photobiostimulation of biological tissue, comprising:

a) a controller unit including a power supply and a control panel having operator input devices and output devices;

b) the controller unit also including a first plurality of treatment radiation sources each providing a respective first radiation beam having a wavelength of between approximately 900 nm and approximately 1100 nm;

c) the controller unit also including a second plurality of aiming radiation sources each providing a respective second radiation beam having a wavelength of between approximately 400 nm and approximately 700 nm; wherein at least one first radiation beam and one second radiation beam concurrently pass through at least one of a plurality of fiber optic cables; and

d) at least two wands each connected to a different one of the plurality of fiber optic cables, the wands including a collimator configured to establish the shape of the emanating coincident radiation beams; wherein the wands are adapted to be arranged in an operative position about the tissue such that the radiation beams emitted from each wand simultaneously pass approximately through a region located in the tissue.

26. A device for photobiostimulation of biological tissue, comprising:

a) a first plurality of treatment radiation sources each providing a respective first radiation beam having a wavelength of between approximately 900 nm and approximately 1100 nm;

b) a second plurality of aiming radiation sources each providing a respective second radiation beam having a wavelength of between approximately 400 nm and approximately 700 nm; wherein at least one first beam and one second beam concurrently pass through at least one of a plurality of fiber optic cables; and

c) at least two wands each connected to a different one of the plurality of fiber optic cables, at least one of the wands including a collimator configured to adjust the focus of the emanating radiation beam;

wherein the wands are adapted to be arranged in an operative position about the tissue such that the radiation beams emitted from each wand simultaneously pass approximately through a region located in the tissue.

27. A device for photobiostimulation of biological tissue, comprising:

a) a treatment radiation source providing a respective first radiation beam having a wavelength of between approximately 900 nm and approximately 1100 nm;

b) a second aiming radiation source providing a respective second radiation beam having a wavelength of between approximately 400 nm and approximately 700 nm; wherein the first beam and second beam concurrently pass through a fiber optic cable; and

c) a wand connected to the fiber optic cable, and including a collimator configured to adjust the focus of the emanating radiation beam;

wherein the wand is adapted to be arranged in an operative position about the tissue such that the radiation beam emitted from the wand illuminates a region located in the tissue.

28. A biostimulation device, comprising:

a) a laser apparatus including a plurality of treatment laser wands each including a collimator with an adjustable focus, the wands being connected to a laser radiation source adapted to emit radiation having a power of between zero and approximately 2.0 watts, an energy of between about 1 joules and about 99 joules, and a wavelength of between approximately 900 nm and 1100 nm; and

b) wherein the laser wands are adapted to be arranged in an operative position to emit the radiation incident to a region of biological tissue for a therapeutically effective length of time.

29. A system for photobiostimulation of biological tissue, comprising:

a) a controller unit including a power supply and a control panel having operator input devices and output devices;

b) the controller unit also including a first plurality of treatment radiation sources each providing a respective first radiation beam having a wavelength of between approximately 900 nm and approximately 1100 nm;

c) the controller unit also including a second plurality of aiming radiation sources each providing a respective second radiation beam having a wavelength of between approximately 400 nm and approximately 700 nm; wherein at least one first radiation beam and one second radiation beam concurrently pass through at least one of a plurality of fiber optic cables; and

d) at least two wands each connected to a different one of the plurality of fiber optic cables, the wands including a collimator configured to adjust the shape of the emanating coincident radiation beams; wherein the wands are adapted to be arranged in an operative position about the tissue such that the radiation beams emitted from each wand simultaneously pass approximately through a region located in the tissue.

30. A method for the treatment of tissue, comprising the steps of:

a) providing at least two infrared laser treatment radiation sources having a wavelength of between approximately 900 nm and approximately 1100 nm;

b) providing at least two sources of aiming laser radiation having a wavelength of between approximately 400 nm and approximately 700 mn;

c) combining the radiation sources so that the radiation of each source is coincident;

d) passing the coincident radiation through at least two optical fibers;

e) providing at least two wands, connected to the optical fibers, wherein at least one wand includes a collimator configured to adjust the shape of an emitted radiation beam;

f) arranging the wands such that the radiation emitted from the wands simultaneously passes through a region located within the tissue; and

g) exposing the tissue to the laser radiation for a therapeutically effective period of time.

* * * * *

US005653706A

United States Patent [19]

Zavislan et al.

[11] Patent Number: 5,653,706

[45] Date of Patent: Aug. 5, 1997

[54] **DERMATOLOGICAL LASER TREATMENT SYSTEM WITH ELECTRONIC VISUALIZATION OF THE AREA BEING TREATED**

[75] Inventors: **James M. Zavislan; Jay M. Eastman,** both of Pittsford, N.Y.

[73] Assignee: **Lucid Technologies Inc.,** Rochester, N.Y.

[21] Appl. No.: **395,223**

[22] Filed: **Feb. 27, 1995**

Related U.S. Application Data

[62] Division of Ser. No. 94,296, Jul. 21, 1993.

[51] **Int. Cl.**[6] **A61B 17/36**

[52] **U.S. Cl.** **606/9**; 606/3; 606/10; 606/17; 606/18; 128/898

[58] **Field of Search** 606/2, 3–6, 9–12, 606/17, 18; 607/88, 89; 128/898

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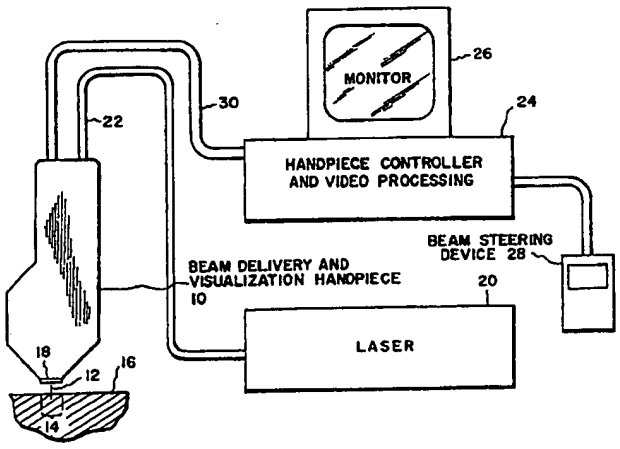
Primary Examiner—Lee S. Cohen
Assistant Examiner—Michael Peffley
Attorney, Agent, or Firm—Kenneth J. LuKacher; M. LuKacher

[57] **ABSTRACT**

A hand held microsurgical instrument for applying laser energy to selected locations (sites) in an area under the skin (or other exposed translucent tissue) to provide localized photothermolysis of underlying tissue at these sites, is described. The laser energy is focused into a spot within the tissue. This spot is of sufficiently small size so that the energy density is sufficient to provide surgical or treatment effects within the tissue without damaging the surface tissue. In dermatology, for example, the technique can be used to destroy endothelial cells in blood vessels which are desired to be removed, such spider veins (nevi) in the skin, hair follicles to prevent hair growth therefrom, or other microsurgical procedures. The area is visualized while the laser beam is steered, using a deflection system, in X and Y coordinates. A telecentric optical system, in which a mirror of the deflection system is located, directs the laser light essentially perpendicular to the area to be treated as the beam is scanned over the area. The optical system also focuses illumination light reflected from the area to a sensor matrix of a CCD video camera. The reflected illumination light is imaged essentially parallel to the optical axis in the object space thereby providing a precise, high resolution image corresponding to the area. The laser beam may be tracked as it is deflected over the area to the selected locations by visualization thereof on a display or monitor associated with the video camera. The locations are then apparent to the treating physician who can then effect an increase of the beam power or turn the beam on so as to treat the tissue in the selected locations.

15 Claims, 9 Drawing Sheets



Appendix R-5

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The Iris Medical Diode Laser Indirect Ophthalmoscope Oculight® SLx Diode Laser System.

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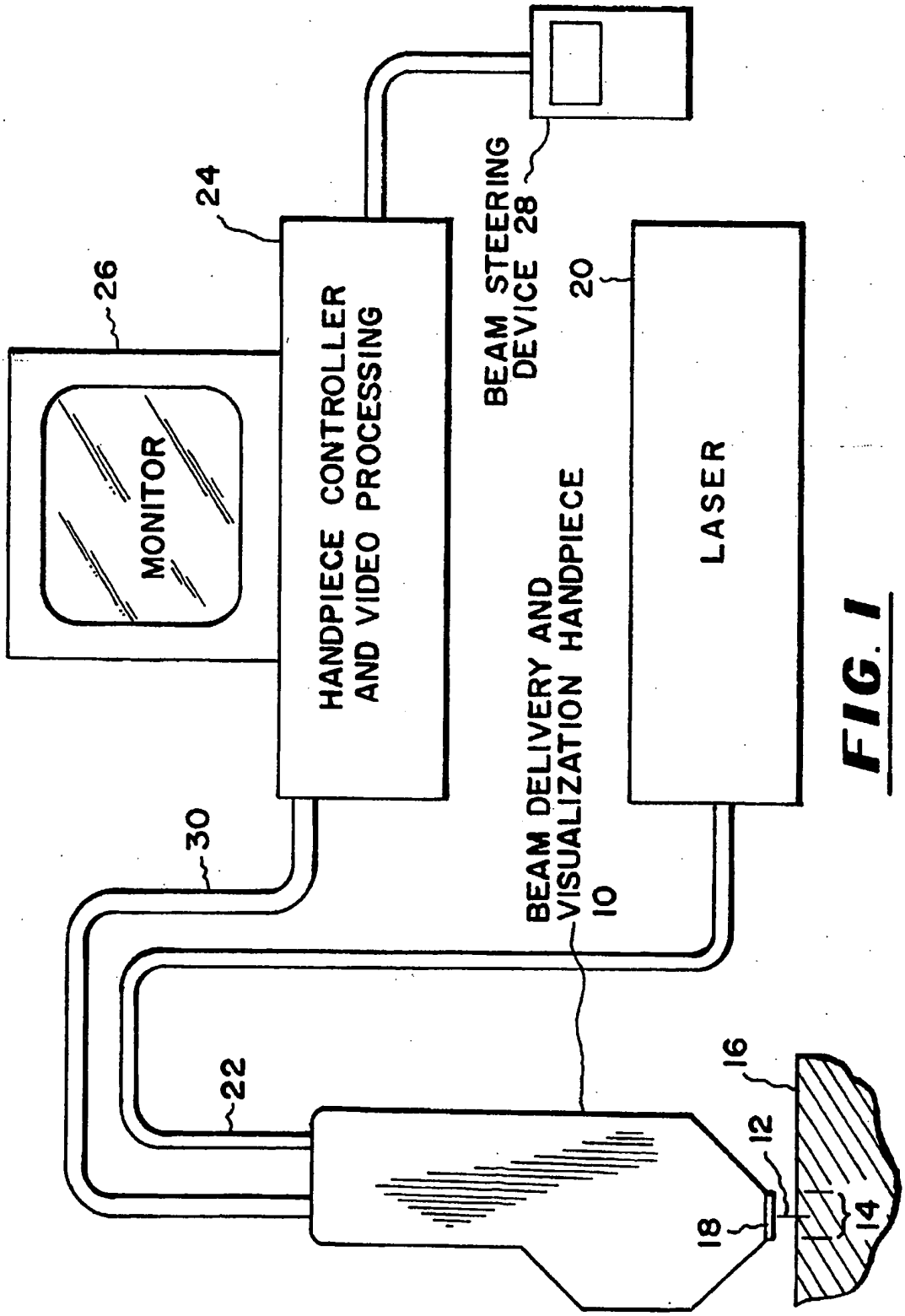
MONITOR
26
HANDPIECE CONTROLLER AND VIDEO PROCESSING
24
BEAM STEERING DEVICE 28
LASER
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BEAM DELIVERY AND VISUALIZATION HANDPIECE
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FIG. 1

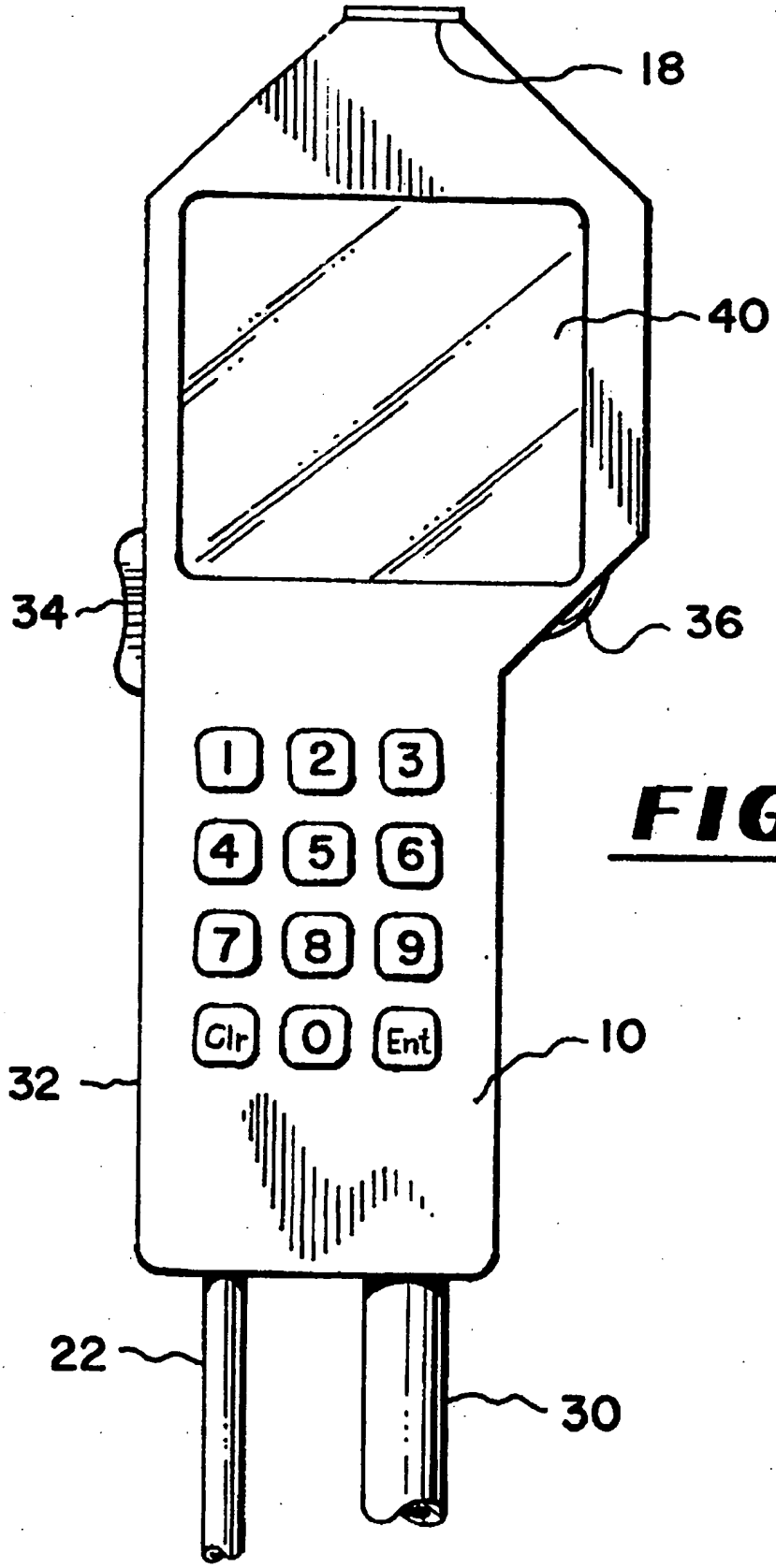

FIG. 2

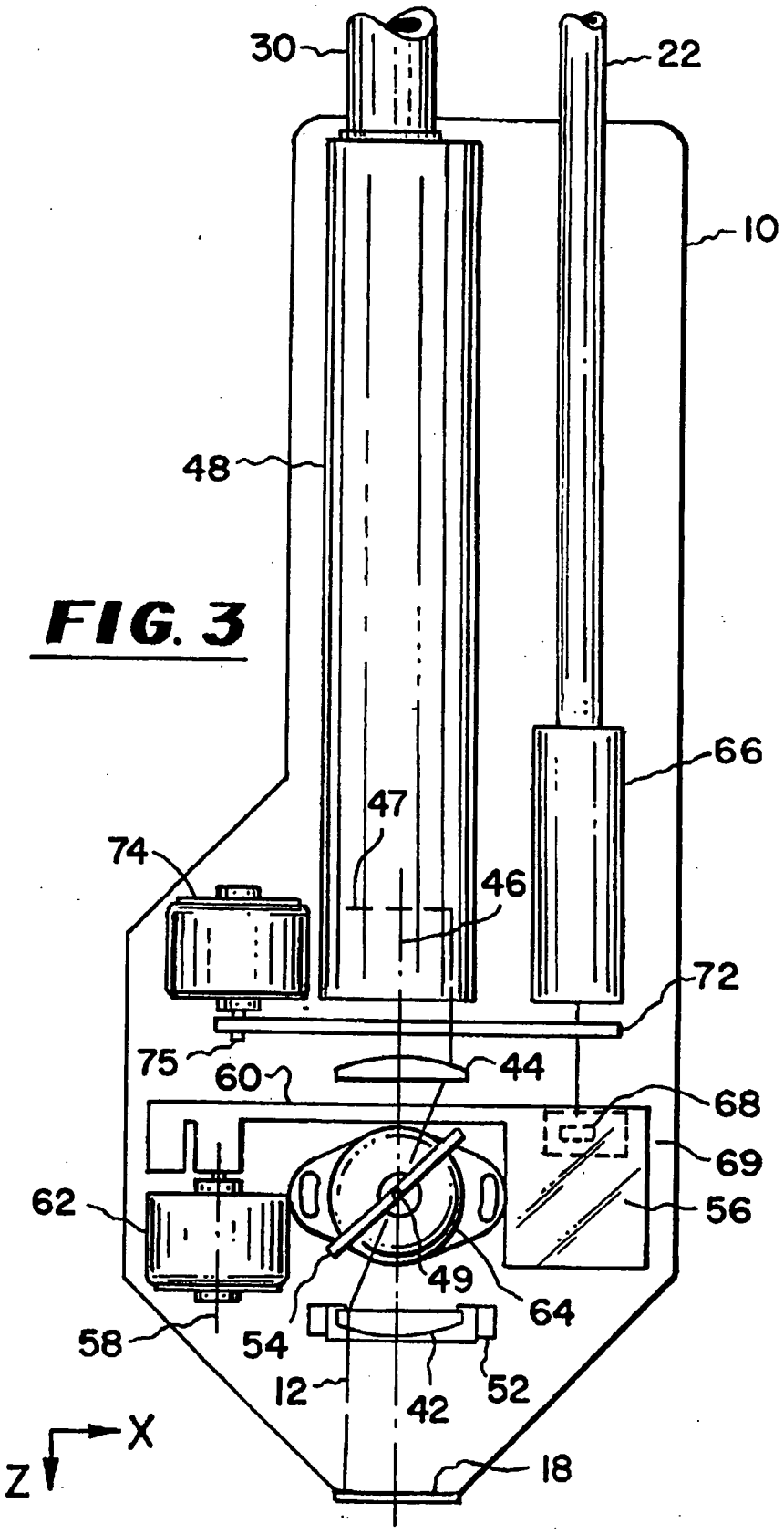
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FIG. 3

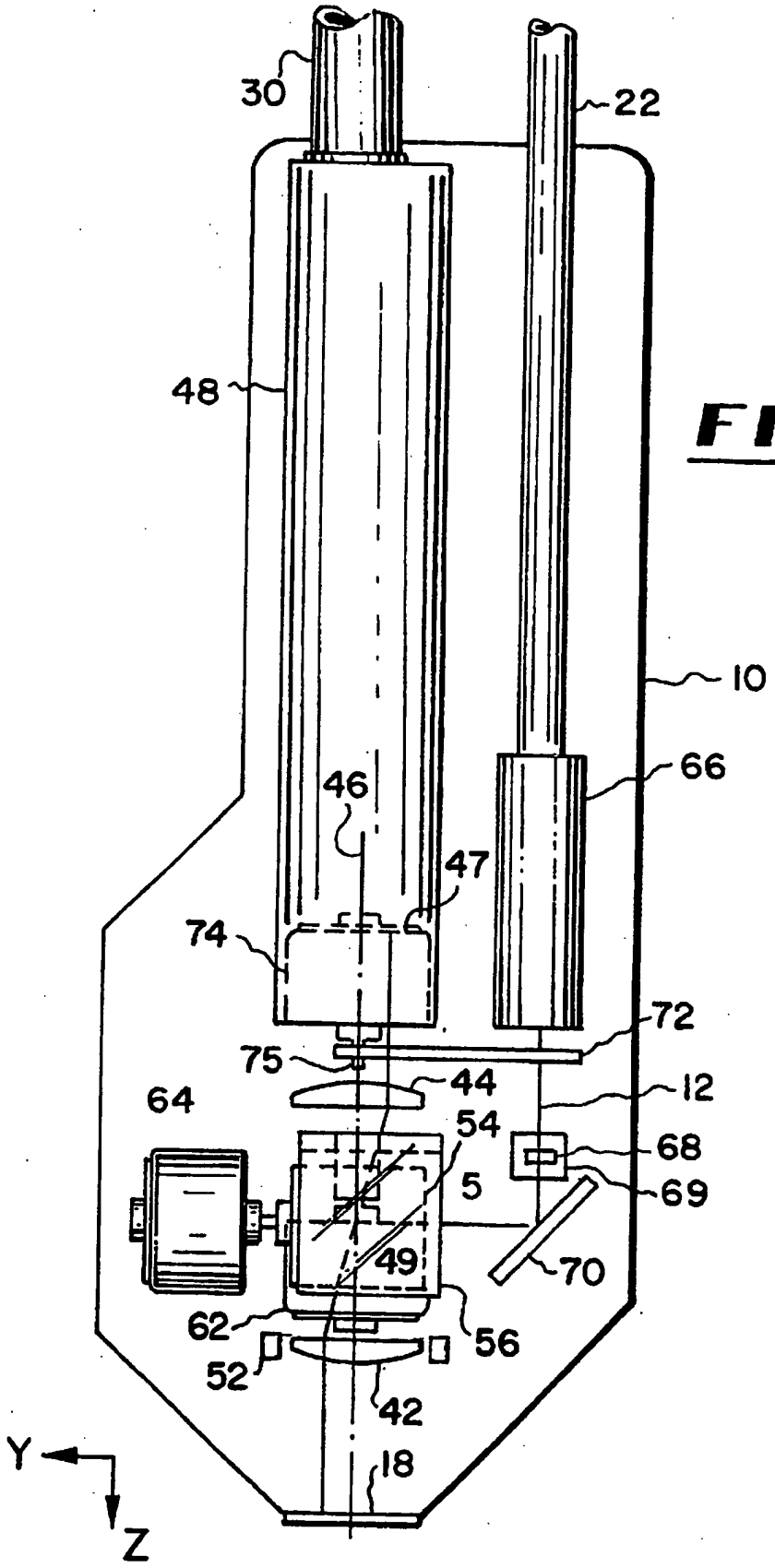
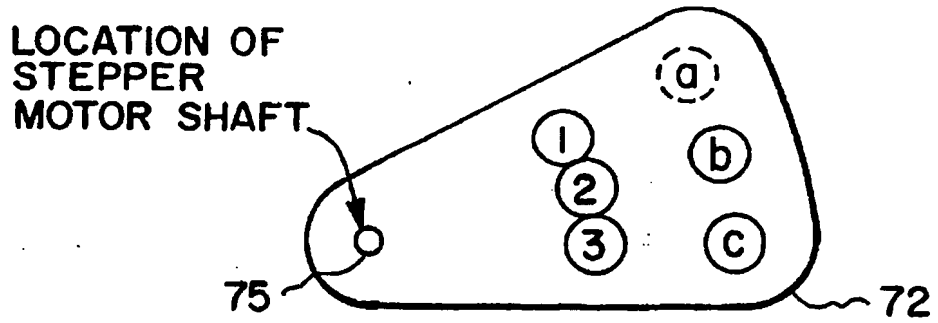


FIG. 4

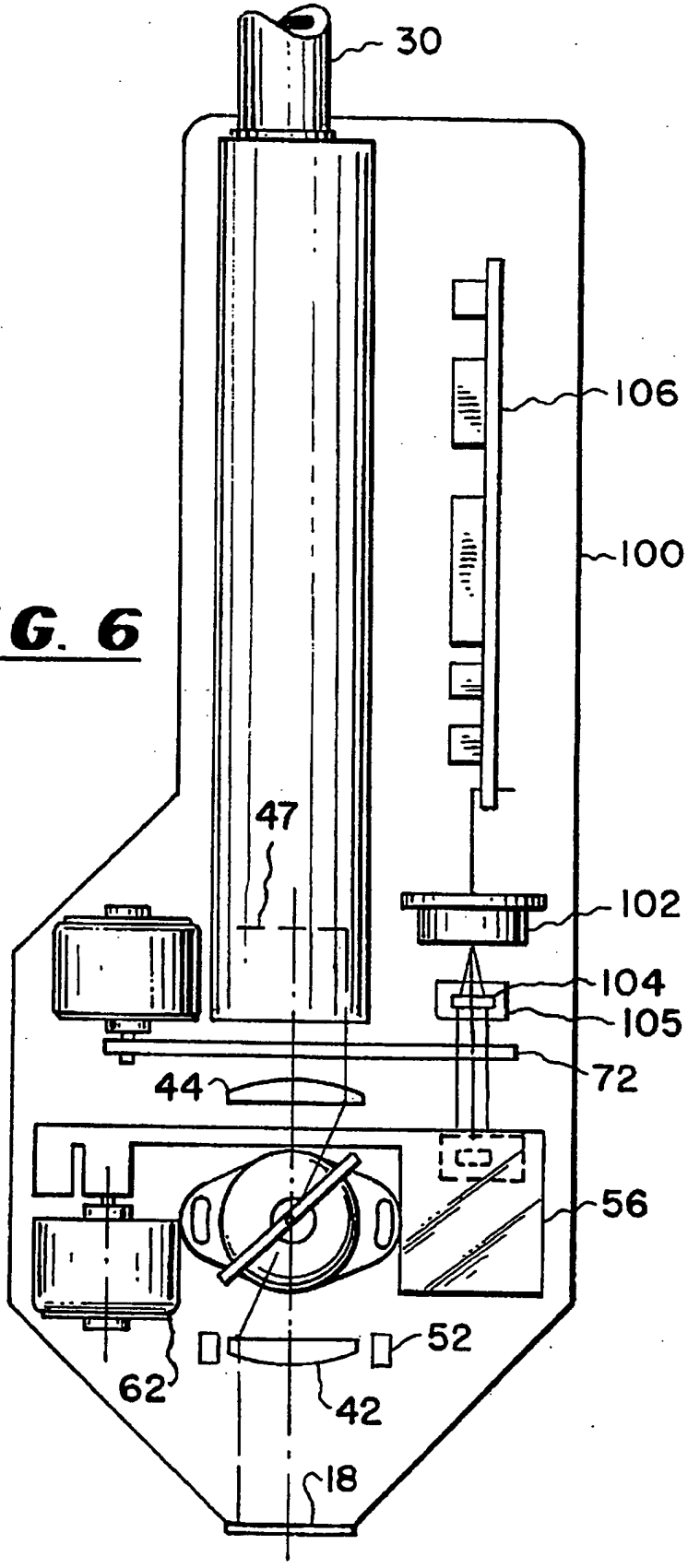


1 = LOCATION OF IR TRANSMITTING OR BLOCKING FILTER FOR VIEWING SYSTEM
2 = LOCATION OF OPEN HOLE (VISIBLE I/R VIEWING)
3 = LOCATION OF NEUTRAL DENSITY FILTER TO PROTECT CCD ARRAY DURING THE TREATMENT PULSE

a = LOCATION OF DENSE BLOCK AND PHOTODETECTOR FOR THE LASER LIGHT
b = LOCATION OF NEUTRAL DENSITY FILTER TO PRODUCE LASER "SPOTTER BEAM"
c = LOCATION OF OPEN HOLE FOR BEAM TREATMENT

FIG. 5

FIG. 6



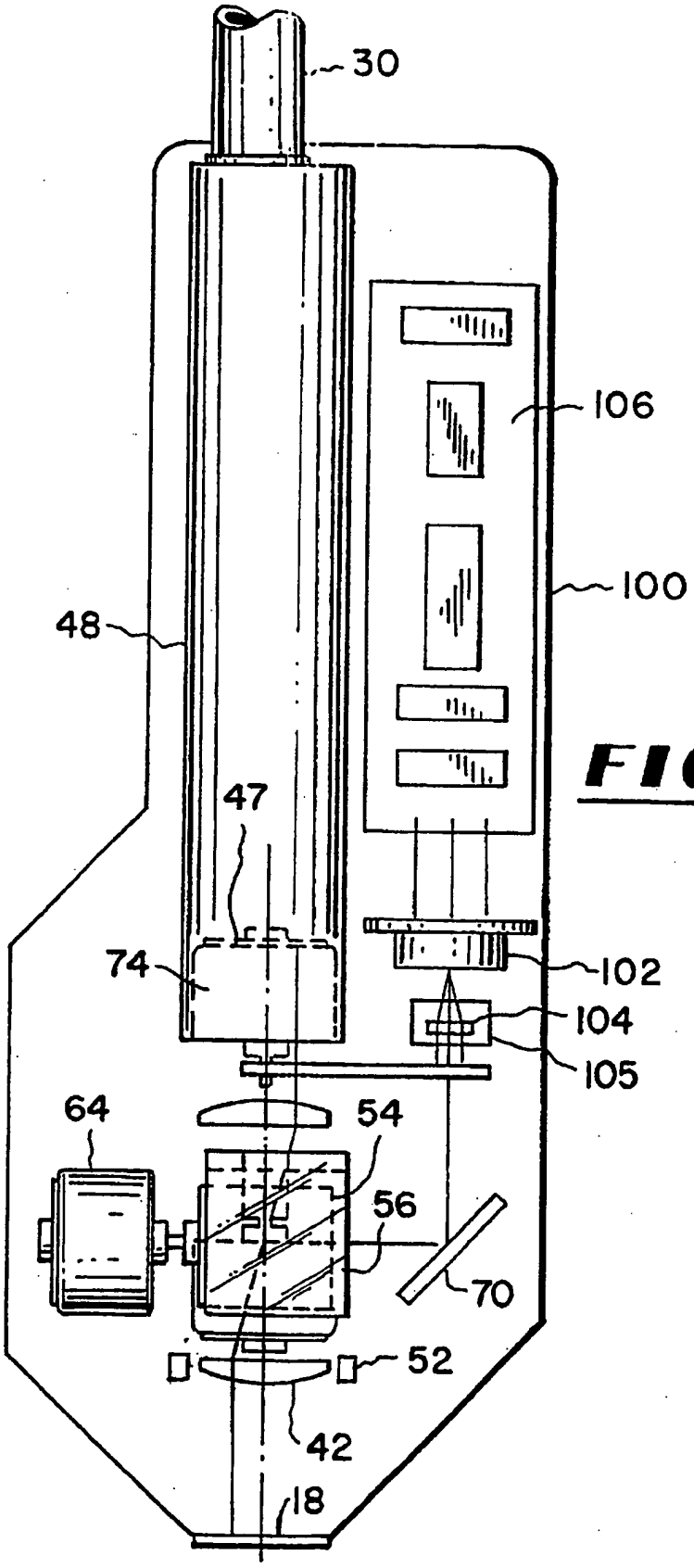
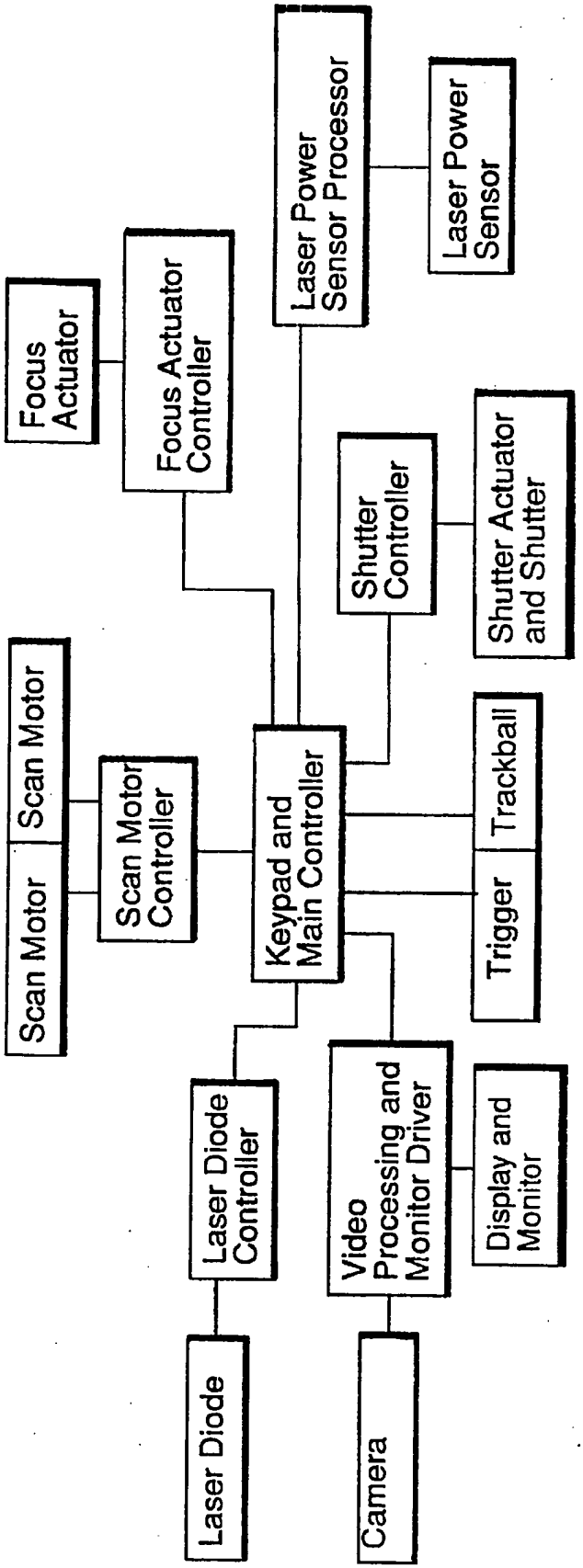


FIG. 7

FIG. 8


Laser Power Sensor Processor
Laser Power Sensor
Focus Actuator
Focus Actuator Controller
Shutter Controller
Shutter Actuator and Shutter
Scan Motor
Scan Motor
Scan Motor Controller
Keypad and Main Controller
Trackball
Trigger
Laser Diode Controller
Video Processing and Monitor Driver
Display and Monitor
Laser Diode
Camera

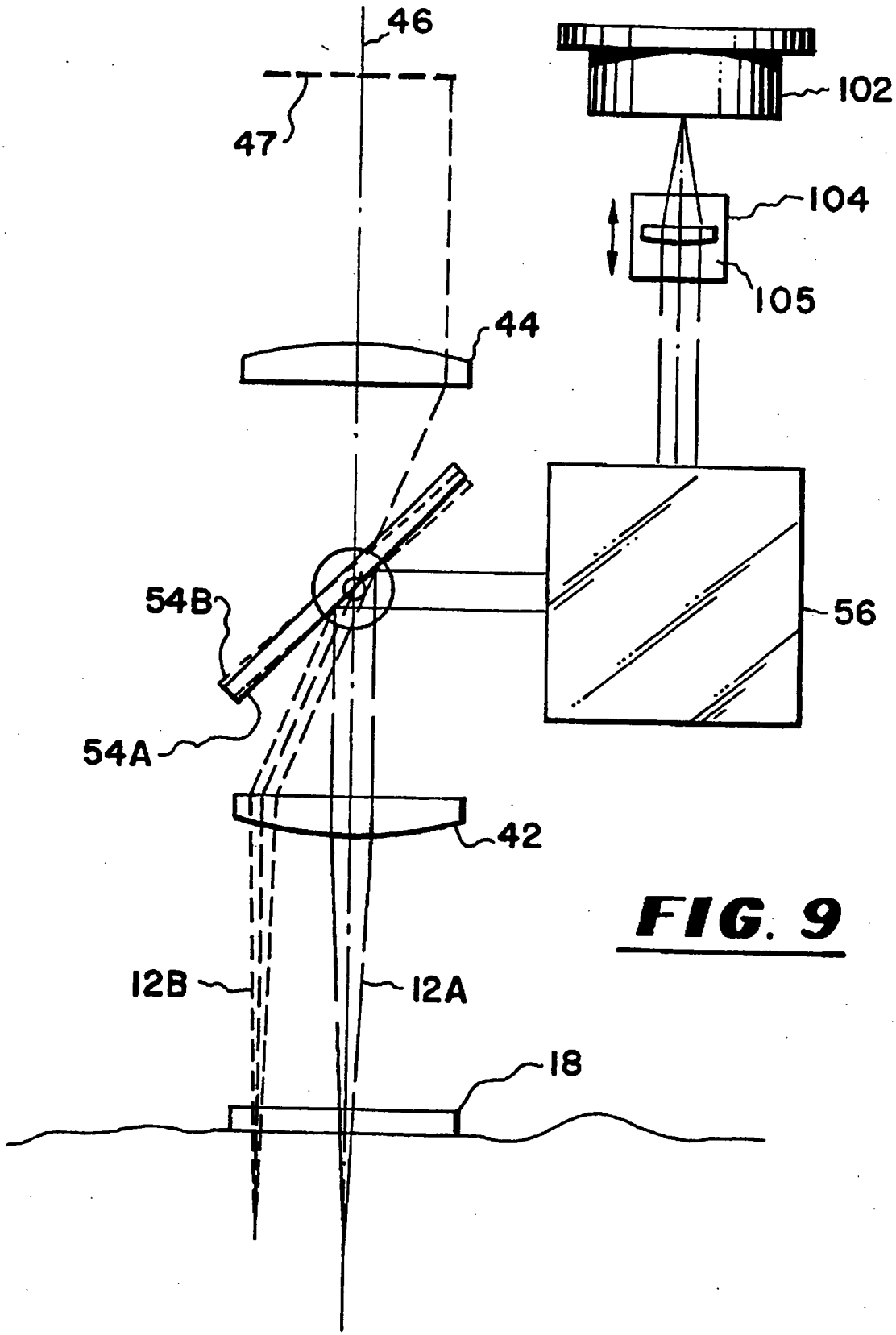


FIG. 9

DERMATOLOGICAL LASER TREATMENT SYSTEM WITH ELECTRONIC VISUALIZATION OF THE AREA BEING TREATED

This is a division of application Ser. No. 08/094,296, filed Jul. 21, 1993 pending.

The present invention relates to a system (method and apparatus) for carrying out microsurgical treatments especially in dermatology and particularly for surgery in selected locations under the surface of the skin or other exposed translucent tissue.

The present invention is especially suitable for providing a hand held instrument from which a laser beam projects. The beam is focused by optics in the instrument at spots within an area selected for treatment and is deflected across the area while the area is visualized using an electronic visualization means which provides, with the beam focusing optics, an image corresponding to the area under treatment. The deflection of the beam is controlled during visualization to place the focus (a spot) at the selected locations. Then the beam power may be increased or the beam turned on, as with a shutter or with means such as filters in the shutter, which can alterably attenuate the beam, while the beam is being located at the treatment sites. These sites may be along the veins such as spider veins which are photothermolyzed and undergo coagulation necrosis. Hair follicles can also be photothermolyzed so as to cause depilation. Other microsurgical procedures, such as to break adhesions between tendons and the surrounding sheath may be carried out using the invention.

Devices for medical treatment have been provided which use laser beams. Also handpieces from which laser beams are projected and manually traced over the skin, which may be compressed under glass slides for protection and heat dissipation purposes, are available. Such devices and treatment techniques generally use laser energy of a wavelength which makes it effective for treatment of lesions, because the lesions selectively absorb that wavelength. The general area containing the lesion is effectively flooded with generally collimated laser light of a wavelength that is highly absorbed by the lesion or the laser beam is moved over the area. Selective absorption of the laser light by the lesion is then responsible for photothermolysis. This technique is called selective photothermolysis and is discussed with respect to the skin in an article by R. R. Anderson and J. A. Parrish which appeared in *Science*, Vol. 220, p. 524, on Apr. 29, 1983. Also, the wavelengths of the laser illumination for selective photothermolysis are subject to scattering and diffusion by the skin. Accordingly, the area exposed to the radiation is heated and may be subject to collateral damage (i.e. reddened or even burned). This produces discomfort to patients and militates against the use of such laser treatment instruments and techniques.

Laser beams have been used for ophthalmological surgery. In such cases, the medium is transparent to the laser beam and can be readily observed through the cornea with ophthalmoscopes. The lens of the eye undergoing treatment may be used to focus the laser beam on the retina. Often the laser beam is manually directed and considerable skill and technique is required for such laser surgery especially to avoid damaging tissue around the site to be treated. It is therefore difficult to precisely deliver the laser energy to the desired sites. See Taboda, U.S. Pat. No. 5,112,328 issued May 12, 1992, for an ophthalmological laser surgery instrument.

The difficulties encountered in laser microsurgery include the lack of a natural focusing mechanism in non-ocular tissues. Also, penetration of the beam so that it is focused and not diffused into a ball shape volume of area too large to concentrate the energy to the level necessary for treatment is faced in all non-ophthalmological laser surgery devices. Also, such devices have not been provided with a visualization system operating at a wavelength appropriate for imaging through turbid, translucent tissue such as skin and other non-ocular tissue, and with sufficient resolving power to enable location of the beam at the selected site where treatment is desired. There have been some suggestions in the area of ophthalmological instruments, but a system including an instrument for other non-ocular microsurgical treatments has not been provided.

It is the principal object of the present invention to provide an improved system for laser assisted microsurgical and especially dermatological treatments in which the treatment area can be visualized while the laser beam is being located at sites in the area where treatment is desired.

It is another object of the present invention to provide an improved system for microsurgery which is automatically operative both for visualization and for location of the laser beam at treatment sites in an area under the skin or other exposed translucent tissue.

It is a still further object of the invention to provide an improved system for microsurgical treatment which utilizes optical energy which is not readily scattered and which can be focused into a spot of sufficiently small area to concentrate the laser beam so that it reaches a level sufficient to provide a photomedical treatment effect.

It is a still further object of the present invention to provide an improved system for microsurgery, especially dermatological surgery which enables coagulation necrosis of spider veins, depilation by cauterization of hair follicles and allows adhesions between tendons and the surrounding sheath to be severed.

It is a still further object of the present invention to provide an improved microsurgery and especially dermatological surgery system using a laser beam of a wavelength which is effective for photothermolysis by virtue of being focused at sites where photothermolysis is desired rather than relying upon selective absorption by chromophores which are selectively absorptive of different wavelengths of optical energy, thereby providing a single instrument using a single wavelength laser beam for different microsurgical and dermatological treatments.

It is a still further object of the present invention to provide an improved system for microsurgery in which heating and burning of the skin or other tissue in the general area being treated is minimized.

It is a still further object of the present invention to provide an improved laser surgery instrument in which an accurate high resolution image is obtained for visualizing and enabling the direction of the beam to selected sites in the area being treated.

Briefly described, a system for thermolysis of tissue in an area under the surface of the skin or other tissue with visualization of the area which is provided in accordance with the invention may be embodied in a housing which is sufficiently small to be hand held. A window in the housing provides a port for illumination of the area under treatment as well as through which the treating laser beam projects. The laser beam may be provided by a laser external of the housing which is introduced into the housing through an optical fiber cable, an articulated optical delivery arm or by a laser, such as a solid state laser (e.g. a laser diode) which is mounted in the housing. The housing contains optical means for projecting and focusing the beam at selected

locations or sites in the area at spots sufficiently small in cross-section, for the power and duration of the beam, to cause localized thermolysis of the tissue at the sites to be treated. There are means in the housing for deflecting the beam to locate the spot at the selected sites one at a time. The housing also has means for visualizing the area while the beam is being deflected, thereby verifying that the spots are at the selected sites before the beam is turned on or its energy increased to cause thermolysis.

The foregoing and other objects, features and advantages of the invention, as well as presently preferred embodiments thereof, will become more apparent from a reading of the following description in connection with the accompanying drawings in which:

FIG. 1 is a block diagram illustrating a dermatological laser treatment system embodying the invention;

FIG. 2 is an enlarged view of the handpiece (the hand held instrument) of the system shown in FIG. 1;

FIG. 3 is a diagram schematically showing the housing and internals of the handpiece illustrated in FIG. 3 when viewed from the front;

FIG. 4 is a view of the housing and the internals of the handpiece, but taken from the right side of FIG. 3;

FIG. 5 is a top view of the shutter of the instrument shown in FIGS. 3 and 4;

FIG. 6 is a view similar to FIG. 3 wherein a laser diode and associated circuitry is used internally of the housing;

FIG. 7 is a view similar to FIG. 4 of the instrument shown in FIG. 6;

FIG. 8 is a block diagram of the electronics of the handpiece shown in FIG. 2; and

FIG. 9 is an optical ray diagram illustrating the telecentric optical system of the instrument which is shown in the preceding figures, which, because it is telecentric, enables the area which is scanned to receive a beam, the central ray of which is generally parallel to the optical axis and to produce an image precisely corresponding to the area.

Referring to FIG. 1, a handpiece 10 contains the laser beam delivery and visualization means which projects and scans a laser beam 12 over an area 14 below the surface of the skin or other non-ocular tissue 16 of a patient requiring treatment. The beam is focused in the area at localized points to provide spots in the area at sites where photothermolysis treatment is required. This area may be in a plane generally perpendicular to the central ray of the beam 12. The plane is also generally parallel to a window 18 at the lower end of the handpiece 10 through which the beam projects. The beam may be scanned stepwise in rectangular or X-Y coordinates over the area 14 to the selected sites.

A feature of the invention is that the beam is focused, and particularly telecentrically focused using telecentric optics. The focus is in the plane of the area 14. Telecentric focusing insures that the central ray is perpendicular to the plane of the area 14. The ray is also parallel to the optical axis of the telecentric optics. A preferred form of the telecentric optics is described hereinafter in connection with FIGS. 3, 4 and 9.

The beam is preferably of a wavelength from 700 to 1300 nanometers (nm) where skin and other non-ocular tissues are translucent and where scattering occurs in the forward direction. Thus the light does not tend to reflect back into the tissue and pile up at the surface of the tissue. This minimizes collateral damage (reddening and even burning) of the skin or surface tissue outside of the treatment zone.

Focusing of the beam minimizes reddening and burning and limits the sites of photothermolysis to the spots in the area where the beam is focused. With a generally collimated or flooding type beam the upper layer of the skin can get hotter and can burn before a lesion (or other tissue at the treatment site) is affected by the laser energy. By focusing the beam, the energy penetrates the skin surface to the site to be treated without heating up the upper layers of the skin, since the intensity of the beam is lower in such upper layers than at the focal point. Thus heating of tissue which is in the path of the beam is minimized.

A laser 20 external of the handpiece 10 may be used to provide the optical treating energy. An optical fiber cable 22 delivers the energy from the laser to the handpiece.

The handpiece visualization means is provided by a video camera having a photoreceptor or sensor, preferably an X-Y matrix of CCD (Charge Couple Device) elements which are in a plane perpendicular to the optical axis of the telecentric optics and in a plane perpendicular to the axis. The central ray of the beam, as focused at the imaging or viewing (visualization) plane in which the photoreceptors are located then arrives perpendicular to the visualization plane. Parallax and similar distortion are avoided and a precise high resolution image is obtained with the video camera in the handpiece 10.

Electronics of the system provides a handpiece controller and video signal processor 24 for the camera. The video signals, after processing, may be displayed on a T.V. monitor 26. A cable 30, containing electrical wires connects the controller and processor 24 to the handpiece 10.

The beam is steered by a beam steering device 28 which may be a joystick, trackball or computer mouse type device. The controller 24 obtains signals from the beam steering device 28 and applies them to a beam deflection system utilizing mirrors and motors which step or steer the beam in X and Y directions. The beam deflection system is described in greater detail hereinafter in connection with FIGS. 3 and 4. The controller applies signals (pulses to the motors of the deflection means) to steer the beam in X and Y to the desired locations in the area 14. Automatically, these locations are focused in the visualization plane and an image is provided by the camera. In addition, the entire area may be flood illuminated, suitably by light containing spectral components of a wavelength which, like the wavelength of the laser beam, penetrates the skin without substantial scattering. The return (retroreflected) light, both from the spot where the laser beam is located and from the illumination, is incident on the visualization plane of the camera and an image of the area as well as of the spot where the beam is focused is obtained. From this image as viewed on the monitor the treating physician can steer the beam to the desired location.

The system is especially suitable for coagulation necrosis of spider veins or spider nevi. The nevi are visualized with visible light and the laser beam is tracked along the veins. The energy is then increased and regions along the vein are subject to photothermolysis. The vein is cut off and the pigment, usually blood, is eventually reabsorbed by the body of the patient.

To epilate using the system, the base of the hair follicle is visualized with an infrared illumination source and video camera and the laser spot positioned over the hair follicle. The laser is then operated, for example a shutter is placed to an open position, and a dose of optical energy of sufficient intensity is delivered at the follicle. With a nominal focal spot of 500 micrometers in diameter and a depth of focus of about 100 micrometers, a dose (or energy density) of about 25 Joules per centimeter squared (J/cm^2) is produced and the hair follicle and its adjacent blood vessels are destroyed by the heat produced by the absorbed laser energy (i.e. photothermolysis occurs). Because of the focusing of the beam, areas of tissue adjacent to the follicle are unaffected.

The controls and even video processing circuitry may be included in the handpiece **10**. FIG. **2** shows a handpiece where the controls and video processing and even the video display (which provides the T.V. image for monitoring purposes) may be provided in the handpiece. FIG. **8** shows the electronic components for carrying out the control and video processing functions.

As shown in FIG. **2**, the handpiece is adapted to be held by its distal or rear end **32** in the hand of the treating physician. This end **32** has a keypad with keys projecting from the surface of the housing for entry of laser control parameters, such as laser power, the duration of the laser bursts or pulses, and depth within the tissue of the focused spot as well as information as to the patient and the treatment afforded. In the position of the fore-finger, there is a trigger button which may operate the laser to turn it on and off and may also operate the shutter which controls the laser energy which is delivered through the window **18** at the proximal end of the handpiece **10**. This trigger may be a two step switch which when depressed to the first step turns the laser on and to the second step actuates a motor which moves the shutter out of a position where it normally blocks the beam for safety purposes. The thumb of the operator may be used to manipulate a trackball **36** which operates an encoder of the type in a computer mouse and provides the beam steering control, and sends signals to the motors of the beam deflecting system.

A display such as a liquid crystal display may be used to present the image which is viewed by the camera, if an external monitor such as the monitor **26** is not used. The resolution obtained by such a display is less than may be desired for certain operations. Then an external large screen monitor **26** is more desirable. The display may also show the parameters which are entered by the keyboard such as laser power and pulse duration. A suitable operating laser power of ¼ watt and a suitable pulse duration (the duration of the burst of CW, IR laser energy) of ¼ second is indicated on the display **40**.

Referring to FIG. **3**, FIG. **4** and FIG. **9** there is shown a first lens **42** and a second lens **44** of telecentric optics. The optics has an optical axis **46** which provides a focus at the plane of the photoreceptors (the image or visualization plane) of a video camera **48**. This camera is preferably a CCD solid state electronic camera having its matrix (an X-Y matrix) located in the image plane **47**. The front or first lens **42** provides a front focus in the plane of the area under treatment (14-FIG. **1**) and a rear focus midway between the back plane of the planoconvex lenses **42** and **44** (that is, the surface or side of these lenses which is planar).

The rear lens **44** has its front focus in the visualization plane **47** and its rear focus midway between the planar surfaces of the lenses **42** and **44**. The midpoint focus is at **49** and intersects the optical axis **46**. The focus **49** is the common rear and front focii of the lenses **42** and **44**, respectively. Because the optics are telecentric, the central ray of the focused beam always remains perpendicular to the plane of the treatment area and the visualization plane **47**, which are perpendicular to the optical axis **46**, even as the beam is scanned over the treatment area. When the beam is retroreflected from the area it is focused in the visualization plane. The visualization plane also receives light which is returned through the telecentric lenses **42** and **44** and which is generated by an annular illuminating ring or lamp **52**. This lamp has a broad spectrum of light but may contain a majority of its intensity in the infrared region including the wavelength of the laser light to allow visualization below the surface of the tissue. Then the entire area and even some of the surrounding area is visualized and an image thereof is obtained with the video camera **48**.

The lenses **42** and **44** form part of the projection means, as does part of the beam deflection or steering means of the system. This deflection and steering means is provided by a first mirror **54** which has an axis of rotation perpendicular to the optical axis **46** and through mid focal point **49** of the lenses **42** and **44**. Preferably, the deflecting or scan mirror **54** is a polarization beam splitter which reflects the incoming laser beam in a direction to propagate out of the handpiece **10** through the window **18**. The return light has a component with an opposite sense of polarization and passes through the scan mirror **54** to the visualization plane **47**.

The scan mirror **54** provides scanning over a first, say the X coordinate of the cartesian coordinates which define the length and width of the area under treatment. Another scan mirror **56** is rotatable about an axis **58**. This mirror is tilted at an angle of approximately 45° such that a ray traveling parallel to the x-axis would be reflected into the plane of the diagram illustrated in FIG. **3**.

The mirror **56** is carried by an arm **60** which is turned by the shaft (about the axis **58**) of a galvanometer type motor **62**, which may be a stepper motor. A similar motor **64** rotates the first scan mirror **54**. The scan mirror **56** deflects the laser beam **12** along the other or Y coordinate. By controlling the motors **62** and **64**, the beam may be located at any selected site in the treatment area and an image of the spot at the site is created at the visualization plane **47** of the camera **48**. Thus, both steering and visualization is accomplished simultaneously and automatically. The two mirror steering or deflection system is generally of the type described in U.S. Pat. No. 5,048,904 issued Sep. 17, 1991 to J. I. Montague, which shows a two mirror scanner.

The laser energy is delivered by the optical fiber cable **22** to a fiber ferrule or coupler **66** from which the incoming beam projects and is focused by a lens **68**. Lens **68** nominally collimates the beam. A focus mechanism **69**, which may be either manual or electromechanical, sets the depth below the surface that the laser light is focused. The focus mechanism **69** moves lens **68** in the z direction relative to ferrule **66**. The beam is folded at a fold mirror **70** and is directed to the polarization sensitive scan mirror **54**. The beam is then focused by the front lens **42** of the telecentric optics to a spot in the area being treated which may be referred to as the treatment plane.

Focusing the beam increases the irradiance of the beam as it propagates to its nominal focus at the spot in the treatment plane. The half angle of convergence is equal to the arc sign of the numerical aperture of the lens **42** $\sin^{-1}$(NA) where NA is the numerical aperture of the focused beam. After transmission through the window the half angle of convergence is reduced to $\sin^{-1}$(NA/n), where n is the refractive index of the tissue. It may be desirable to use the window **18** as a contact plate. Then the material of the window is desirably of high thermal conductivity and is approximately matched to the refractive index of the skin or other tissue (n in the range of approximately 1.35 to 1.55).

Consider the case where the laser has a wavelength of 950 nm, the absorption coefficient of the tissue in the layers under the surface to the treatment area is μ's which is 0.1 mm^{-1}, the scattering coefficient μ's is 10 mm^{-1}. The tissue may have a anisotropy factor g of 0.985. The reduced scattering coefficient μ_s is then 0.15 (i.e. the reduced scattering coefficent $\mu_s=\mu_s(1-g)$. If the treatment area is 3 mm below the surface of the skin the approximate spot size considering scattering is about 500 micrometers. This is a size which is within the diameter of spider veins and

approximately equal to the region at the base of a hair follicle. For a numerical aperture of the focused beam of 0.3, approximately 40% of the incident power from the coupler **66** is delivered in the treatment area. Because of the half angle of convergence the intensity is spread over a much larger area between the surface of the skin and the treatment area. It is believed that the safety margin for avoiding excessive heating which might cause surface tissue damage is 33% of the power delivered from the coupler **66**, the beam focused with a lens having a numerical aperture of 0.3 provides a intensity or laser dose (i.e., energy density) above the depth of focus at the treatment area (and the treatment plane) which is sufficient to avoid damage to the tissue above the treatment sites, in the foregoing example.

For personnel safety, protection of the camera **48** and for visualization a shutter **72** is provided by an arm which is rotated in a plane perpendicular to the optical axis **46** by a motor **74**, which may be similar to the motors **62** and **64**. This shutter **72** is shown in plan view in FIG. **5**. The shutter has two sets (a, b, c and **1**, **2**, **3**) of three regions which provide different transmisivity during different modes or stages of operation of the system. The normal or unpowered position of the shutter is with the region **1** in the path of the retroreflective light to the visualization plane **47** in the camera and with the region a (a dense block or no hole at all through the shutter) intercepting the output beam from the coupler **66**. This dense block may preferably include a photodetector used to monitor the beam power eminating from ferrule **66**. Then the illumination from the lamp **52** can be turned on and the area viewed. This mode or stage of operation may be used to move the instrument to find the desired area without any laser illumination.

When the area has been found the shutter is moved so that the incoming beam is intercepted at region b, containing a neutral density filter which attenuates the laser beam in the path of the output beam from the coupler **66**. The region **2** is then in the path of the return light from the spot where the laser beam is focused in the treatment plane. The region **2** may be an open hole. This permits both visible viewing and viewing of the infrared (700 to 1300 nm wavelength illumination) due to the laser beam. In this position of the shutter the system utilizes the laser beam as a spotter or tracking beam to locate the sites to be treated, say a hair follicle or a part of a spider vein to be coagulated, or an adhesion between a tendon and its sheath.

Finally, the shutter is moved to its furtherest position (in a counter clockwise direction in FIG. **5**) about the axis **70** of rotation of the shaft **75** of the motor **74**. Then, the output beam **66** passes through an open hole c, while a neutral density filter (region **3**) is interposed in the return path to protect the television camera (especially the CCD sensor array) during the treatment pulse.

Referring to FIGS. **6** and **7**, a hand piece **100** is shown which is identical so far as its visualization and beam projection system is concerned and like parts are identified by like referenced numerals. An external laser is not used. Rather a laser diode **102** is used to produce the infrared radiation. The output of the diode is nominally colliminated by a lens **104** to provide a beam to the fold mirror **70** and thence to the deflection mirrors **56** and **54**. The lens **104** mounted to focus mechanism **105**, which may be manual or electromechanical, sets the depth below the surface of the tissue to which the laser light is focused. The electronics on which the laser diode **102** may be mounted and also which contains the controller and video processing circuitry is a printed circuit board **106**. The components of the circuitry will be more apparent from FIG. **8**.

From the foregoing description it will be apparent that there has been provided an improved system (method and apparatus) for microsurgical and especially dermatological treatment which enables visualization of the area being treated as well as provide safety for the patient and the user of the system. Variations and modifications in the herein described system, within the scope of the invention, and numerous other microsurgical procedures than described herein, will undoubtedly suggest themselves to those skilled in the art. Accordingly, the foregoing description should be taken as illustrative and not in a limiting sense.

We claim:

1. A method for coagulation of vessels in dermal tissue comprising the steps of:

scanning said tissue with a single laser beam at a wavelength from 700 to 1300 nanometers which propagates through optics to select locations of at least one of said vessels in said tissue;

stopping said laser beam at each of said locations while said scanning step is carried out;

focusing said laser beam through said optics to form a spot to cause coagulation of said vessel at each of said locations while said stopping step is carried out; and

visualizing said laser beam while said scanning step is carried out.

2. The method according to claim **1** wherein said scanning step further comprises the step of scanning step-wise in X-Y coordinates said laser beam over an area of said tissue to select locations of at least one of said vessels in said tissue.

3. The method according to claim **1** further comprising the step of controlling said laser beam to operate within defined operational parameters while said scanning step is carried out.

4. The method according to claim **1** wherein said laser beam is operated at wavelengths translucent to said tissue.

5. A method for microsurgery in translucent tissue by thermolysis of internal lesions with a laser beam which comprises the steps of:

projecting said beam at a wavelength from 700 to 1300 nanometers with energy density less than sufficient to cause thermolysis of said tissue to locate a plurality of locations in an area where treatment is carried out; visualizing said area with a solid-state electronic camera which receives light reflected from said area to track said beam while said projecting step is carried out;

stopping said beam at each of said locations; and

focusing said beam to form a spot of sufficiently small cross-section to cause localized thermolysis of the lesion at said locations in said area;

enabling said laser beam while it is stopped at said locations to radiate said focused spot at said locations with energy density sufficient to cause thermolysis of tissue at said locations.

6. The method according to claim **5** wherein said visualizing step further comprises the step of providing television pictures of said area on a video display connected to said solid-state electronic camera.

7. The method according to claim **5** further comprising the steps of altering the intensity of said beam between a level sufficient for visualization of said area with said beam during said visualizing step and a level which provides a photomedical effect so as to enable said beam to be tracked for finding said locations for treatment, and increasing said level when said locations are found to treat said tissue at said locations.

8. The method according to claim 5 wherein said area is under the surface of the skin and said laser beam is of a wavelength causing scattering of said beam by tissue under the surface essentially in the same direction as the direction of which said beam propagates.

9. The method according to claim 5 wherein said beam is of an infrared (IR) wavelength where said tissue is generally translucent to said beam.

10. The method according to claim 5 wherein said projecting step is carried out by deflecting and focusing said beam to move said spot in X, Y and Z directions to locate said spot at different ones of said locations.

11. A method for microsurgery in translucent tissue by thermolysis of internal lesions with a laser beam which comprises the steps of projecting a single laser beam at a wavelength from 700 to 1300 nanometers with energy density less than sufficient to cause thermolysis of said tissue to locate a plurality of locations in an area where treatment is carried out, visualizing said area to track said beam while said projecting step is carried out, stopping said beam at each of said locations, focusing said beam to form a spot of sufficiently small cross-section to cause localized thermolysis of the lesion at said locations in said area, and enabling said laser beam while it is stopped at said locations to radiate said focused spot at said locations with energy density sufficient to cause thermolysis of tissue at said locations.

12. The method according to claim 11 further comprising the steps of altering the intensity of said beam between a level sufficient for visualization of said area with said beam during said visualizing step and a level which provides a photomedical effect so as to enable said beam to be tracked for finding said locations for treatment, and increasing said level when said locations are found to treat said tissue at said locations.

13. The method according to claim 11 wherein said area is under the surface of the skin and said laser beam is of a wavelength such that scattering of said beam by tissue under the surface is essentially in the same direction as the direction of which said beam propagates.

14. The method according to claim 11 wherein said beam is of an infrared (IR) wavelength where said tissue is generally translucent to said beam.

15. The method according to claim 11 wherein said projecting step is carried out by deflecting and focusing said beam to move said spot in X, Y and Z directions to locate said spot at different ones of said locations.

* * * * *

TITLE

Multi-Probe Laser Device

FIELD OF INVENTION

[0001] This invention relates generally to medical devices that employ lasers. More particularly, this invention relates to a laser light generator device that has multiple probes, enabling multiple different treatments to be made simultaneously.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0002] This application claims the benefit of co-pending U.S. Application No. 09/932,907 filed 08/20/2001 which claims the benefit of U.S. Provisional Application No. 60/273,282 filed March 2, 2001.

BACKGROUND

[0003] Low energy laser therapy (LLLT) is used in the treatment of a broad range of conditions. LLLT improves wound healing, reduces edema, and relieves pain of various etiologies, including successful application post-operatively to liposuction to reduce inflammation and pain. LLLT is also used during liposuction procedures to facilitate removal of fat by causing intracellular fat to be released into the interstice. It is also used in the treatment and repair of injured muscles and tendons.

[0004] LLLT utilizes low level laser energy, that is, the treatment has a dose rate that causes no immediate detectable temperature rise of the treated tissue and no macroscopically visible changes in tissue structure. Consequently, the treated and surrounding tissue is not heated and is not damaged. There are a number of variables in laser therapy including the wavelength of the laser beam, the area impinged by the laser beam, laser energy, pulse width, treatment duration and tissue characteristics. The success of each therapy depends on the relationship and combination of these variables. For example, liposuction may be facilitated with one regimen utilizing a given wavelength and treatment duration, whereas pain may be treated with a regimen utilizing a different wavelength and treatment duration, and inflammation a third regimen. Specific devices are known in the art for each type of therapy.

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[0005] Often it is desirable to treat a patient for multiple types of problems during a single treatment. Because specific therapies require different regimen, treating multiple problems currently requires multiple separate laser devices. It is desirable to provide a device that enables multiple types of treatments with a single device. It is also desirable to be able to provide multiple treatments simultaneously with a single device, in different areas of a patient's body.

[0006] Therefore, an object of this invention is to provide a laser therapy device that enables multiple types of treatments. It is another object to provide a single device that provides these treatments simultaneously. It is another object of this invention to provide an apparatus that can simultaneously emit multiple beams of laser light that can be applied to multiple areas of a patient's body. It is another object of this invention to provide an apparatus that can simultaneously emit laser light in multiple different pulse widths. It is a further object of this invention to provide an apparatus that can simultaneously emit laser light in multiple beam shapes and spot sizes. It is a particular object of this invention to provide a hand-held therapeutic laser device to provide low level laser therapy which can be used to simultaneously facilitate liposuction, treat post-operative inflammation and pain, and treat and repair injured muscles and tendons.

SUMMARY OF THE INVENTION

[0007] This invention is an improved hand-held laser device that can simultaneously provide multiple types of low level laser therapy treatments to multiple areas of a patient's body simultaneously. The device enables laser light of different pulse widths, different beam shapes and spot sizes to be applied to a patient's body. The device includes multiple laser sources. In the preferred embodiment, two semiconductor diode laser sources simultaneously provide two separate laser beams from separate probes, one laser beam producing laser light at a first pulse width and the other producing laser light at a second pulse width.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is a schematic illustration of a preferred embodiment of the present invention.

[0009] FIG. 2 is a schematic view of the optical arrangement producing a line spot shape of the preferred embodiment.

[0010] FIG. 3 is a schematic view of the optical arrangement producing a circular spot shape of the preferred embodiment.

[0011] FIG 4 is a schematic illustration of a preferred embodiment of the present invention, where the dotted line defines the components disposed in each probe.

[0012] FIG 5 is a schematic illustration of an alternate embodiment of the present invention, where the dotted line defines the components disposed in each probe.

[0013] FIG. 6 is a schematic illustration of an alternate embodiment of the present invention, where the dotted line defines the components disposed in each probe.

[0014] FIG. 7 is a schematic illustration of application of low-level laser radiation using the preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0015] Referring to the drawings, there is illustrated a hand-held laser device designated generally as 10. The device includes one or more laser energy sources, a power source, at least two optical arrangements, one or more control circuits, and at least two hand-held aiming devices, referred to herein as probes. Fig. 1 shows the preferred embodiment in which a first probe 11 and a second probe 12 are connected to a base 14, which includes a power source 15 (not shown). The base 14 is typically a hand-held unit, but it may also be a stationary unit that typically sits on a table or the ground, functioning as a central base from which many probes may be employed.

[0016] The preferred embodiment comprises a first laser energy source 21 for emitting light from the first probe 11 and a second laser energy source 22 for emitting light from the second probe 12. The laser energy sources 21 and 22 are connected to the power source 15. The power source preferably provides direct current, such as that provided by a battery, but may instead provide alternating current such as that provided by conventional building current which is then converted to direct current. These laser energy sources can be energized independently or simultaneously, which throughout this specification refers to acts occurring at generally at the same time.

[0017] The first laser energy source 21 and second laser energy source 22 each produce a laser beam which exits the laser and is shone through optical arrangements 41 and 42, respectively, that produce beam spots. The beam spot is the cross-sectional shape and size of the emitted beam as it exits the optical arrangement. For example, a laser beam of circular cross-section creates a circular beam spot as the laser light impinges the patient's skin. If the laser light emitted is in the visible range, a circular spot can be seen on the patient's skin of substantially the same diameter as the laser beam emitted from the optics arrangement. Various beam spot shapes can be created, including a line, a circle, an ellipse, a plus-sign, or combination of any of them. The probes may product different spot shapes, or have the same spot shapes.

[0018] In the preferred embodiment, the first laser beam is passed through a first optical arrangement that generates a beam of substantially linear cross-section, resulting in a line of laser light seen on the patient's skin. The second laser passes through a second optical arrangement that generates a beam of circular cross-section, resulting in a circular spot shape as seen on the patient's skin. Fig. 2 illustrates the first optical arrangement 41 of the preferred device, which includes a collimating lens 44 and a line generating prism 45. The collimating lens 44 and the line generating prism 45 are disposed in serial relation to the laser energy source 21. The collimating lens 44 and the line generating prism 45 receive and transform the generated beam of laser light into the line of laser light L. As an alternative, a suitable electrical or mechanical arrangement could be substituted for the optical arrangement 41.

[0019] As shown in Fig. 3 the second optical arrangement 42 of the preferred device includes a collimating lens 46 and a beam spot shaping lens 47. As with the first optical arrangement, the collimating lens 46 and beam spot shaping lens 47 are disposed in serial relation to the second laser energy source 22. The collimating lens 46 and beam spot shaping lens 47 receive and transform the generated beam of laser light into a circular beam spot of laser light C. As an alternative, a suitable electrical or mechanical arrangement could be substituted for the optical arrangement 42 to achieve a desired spot shape.

[0020] Control circuitry is connected to the laser energy sources to control whether the lasers are on or off, how long the lasers are powered on, the duration of each pulse of

laser light emitted, and the period of time between one pulse starting and the next pulse starting, referred to herein as the pulse width. Typically the control circuitry is digital, in discrete or integrated circuits, as is known in the art, but analog circuits can also be employed. In the preferred embodiment there are separate control circuits for each probe. Control circuits 31 and 32 are connected to the laser energy sources 21 and 22, respectively, to control the various parameters of the emissions. For ease of reference, pulse widths can be referred to in shorthand notation in cycles/second, or Hz. Pulse widths from 0 to 100,000 Hz may be employed to achieve the desired effect on the patient's tissue. At 100,000 Hz, the pulse width is 0.00001 second. At 0 Hz, a continuous beam of laser light is generated. The goal for LLLT regimen is to deliver laser energy to the target tissue utilizing a pulse width short enough to sufficiently energize the targeted tissue and avoid thermal damage to adjacent tissue.

[00021] The probes have an interior cavity. In the preferred embodiment, the first laser energy source 21 and first optical arrangement 41 are contained in the first probe 11 and the second laser energy source 22 and second optical arrangement 42 are contained in the second probe 12, while the power source 15 and control circuitry 31 and 32 are contained within the base 14. See Fig. 4, which illustrates the configuration of the components of the invention as they relate to each probe, and where the dotted line 17 indicates the components disposed in the first probe and dotted line 18 indicates the components disposed in the second probe. Alternatively, the laser energy source, optical arrangement, and control circuitry can be housed in the probe. That is, the first laser energy source 21, the first optical arrangement 41, and the control circuitry for the first probe 31 are contained in the first probe 11, and the second laser energy source 22, the second optical arrangement 42, and the control circuitry for the second probe 32 are contained in the second probe 12, as the power source 15 remains within the base 14. See Fig. 5 in which dotted lines 17 and 18 again indicate the components that are in the probes. Fig. 6 shows another alternate configuration, in which a single laser energy source 23, a single control circuitry 33 for the first probe and the second probe, and the power source 15 are contained in the base 14, and the probes contain only the optical arrangement for the first probe 41 and the optical arrangement for the second probe 42,

respectively. Again, the dotted lines 17 and 18 indicate which components are in the probes.

[0022] Laser energy sources are known in the art for use in low-level laser therapy. Visible light in about the 400-700 nm range is preferred, and the frequency is determined by the particular therapy given to the patient. The laser energy sources include Helium-Neon lasers having a 632 nm wavelength and semiconductor diode lasers with a broad range of wavelengths between about 600-800 nm. The laser energy sources in the preferred embodiment are two semiconductor laser diodes that produce light in the red range of the visible spectrum, having a wavelength of about 635 nm. Other suitable wavelengths are used for other particular applications. While many LLLT regimen include visible laser light, it may be advantageous to utilize ultraviolet (approx. 1-400 nm) or infrared (approx 700 – 10^5 nm) laser energy, again depending on the type of treatment desired. Solid state and tunable semiconductor laser diodes may also be employed to achieve the desired wavelength.

[0023] Different therapy regimens require diodes of different wattages. The preferred laser diodes use less than one watt of power each to simultaneously facilitate liposuction, treat post-operative inflammation, and post-operative pain. Diodes of various other wattages may also be employed to achieve the desired laser energy for the given regimen.

[0024] Fig. 7 illustrates the device in use. A practitioner 70 treats one area of the patient 71 with the first probe 11 and treats a different area of the patient 71 with the second probe 12.

[0025] While there has been illustrated and described what is at present considered to be a preferred embodiment of the present invention, it will be understood by those skilled in the art that various changes and modifications may be made, and equivalents may be substituted for elements thereof without departing from the true scope of the invention. Therefore, it is intended that this invention not be limited to the particular embodiment disclosed as the best mode contemplated for carrying out the invention, but that the invention will include all embodiments falling within the scope of the appended claims.

ABSTRACT

A hand-held laser device that can simultaneously provide multiple types of low level laser therapy treatments to multiple areas of a patient's body simultaneously. The device enables laser light of different pulse widths, different beam shapes and spot sizes to be applied to a patient's body. The device includes multiple laser sources. In the preferred embodiment, two semiconductor diode laser sources simultaneously provide two separate laser beams from separate probes, one laser beam producing laser light at a first pulse width and the other producing laser light at a second pulse width.

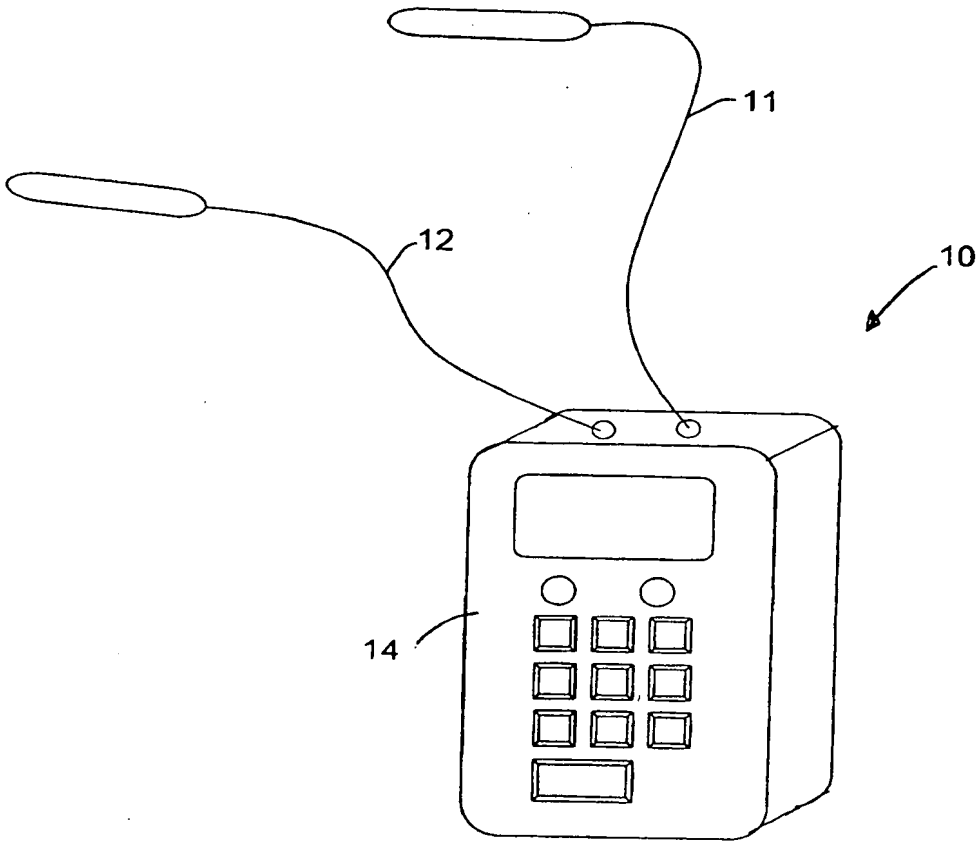


FIG. 1

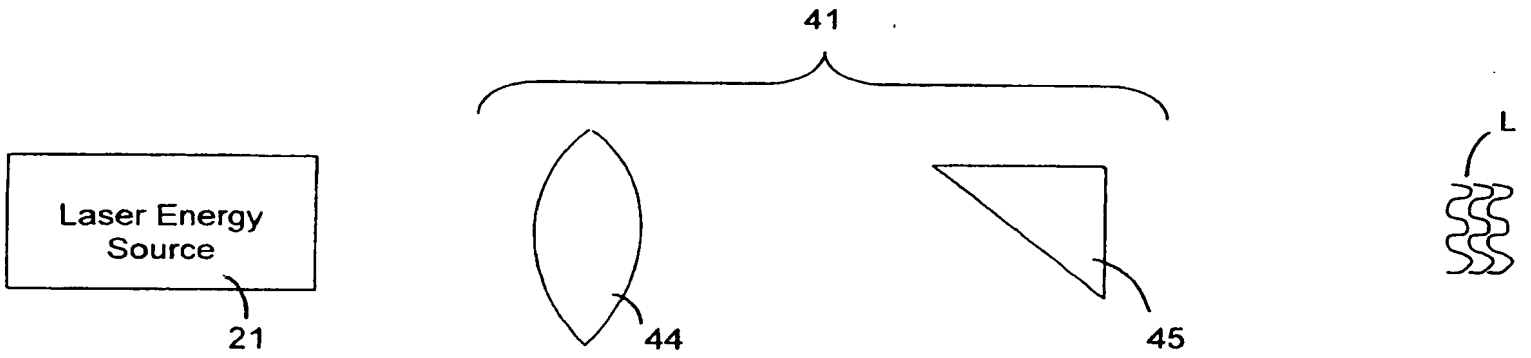

41
Laser Energy Source
21
44
45
L

FIG. 2

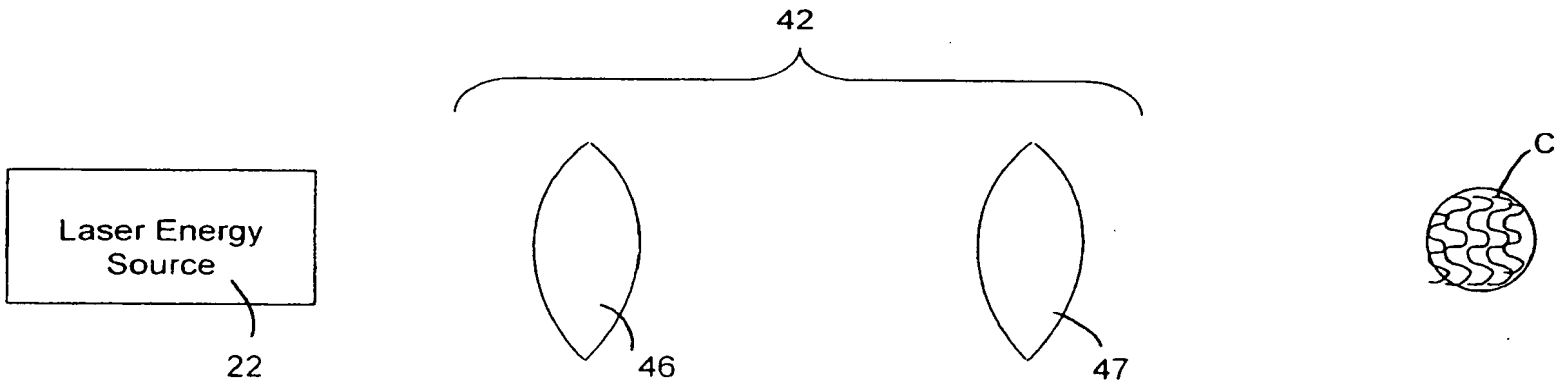
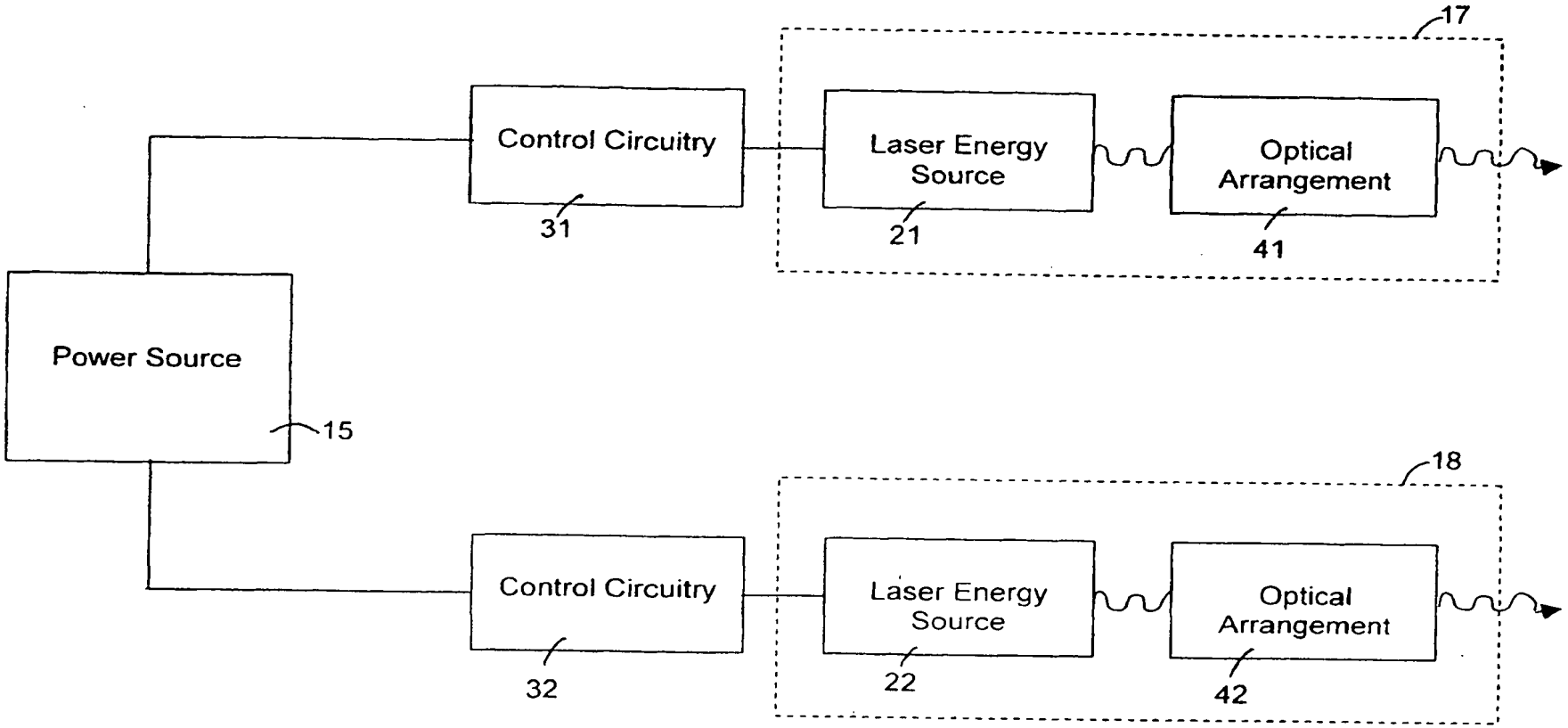

42
Laser Energy Source
22
46
47
C

FIG. 3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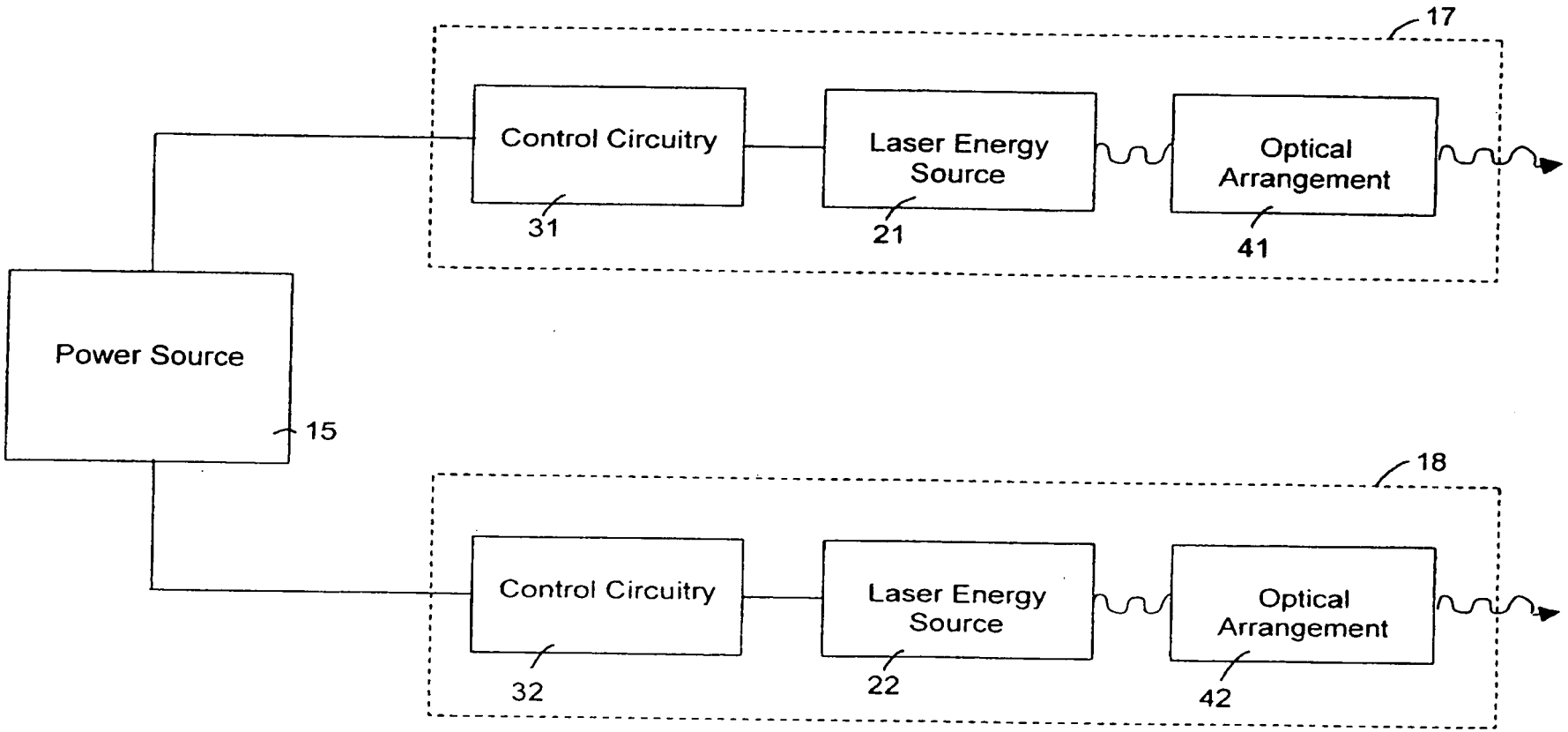
Control Circuitry
31
Laser Energy Source
21
Optical Arrangement
41
Power Source
15
18
Control Circuitry
32
Laser Energy Source
22
Optical Arrangement
42

FIG. 4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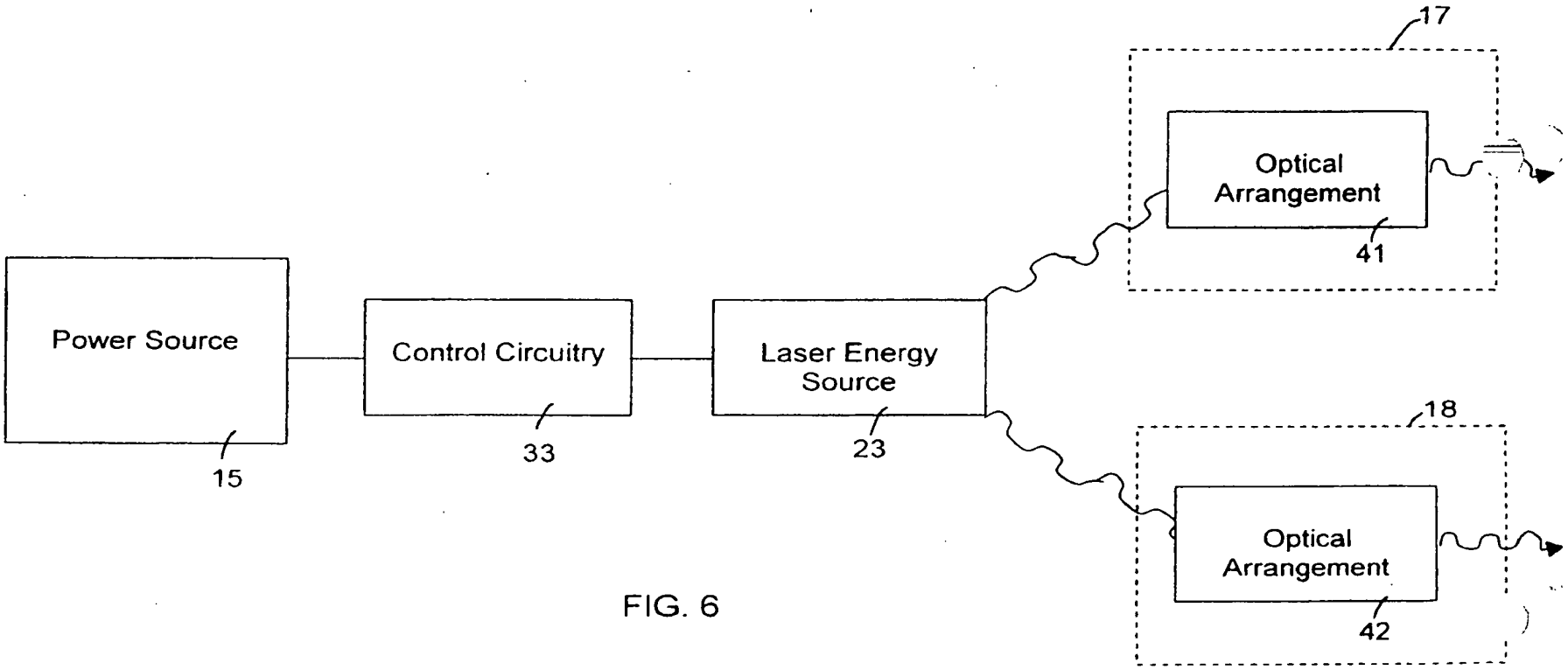
Control Circuitry
Laser Energy Source
Optical Arrangement
31
21
41
Power Source
15
18
Control Circuitry
Laser Energy Source
Optical Arrangement
32
22
42

FIG. 5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Optical Arrangement
41
Power Source
Control Circuitry
Laser Energy Source
15
33
23
18
Optical Arrangement
42

FIG. 6

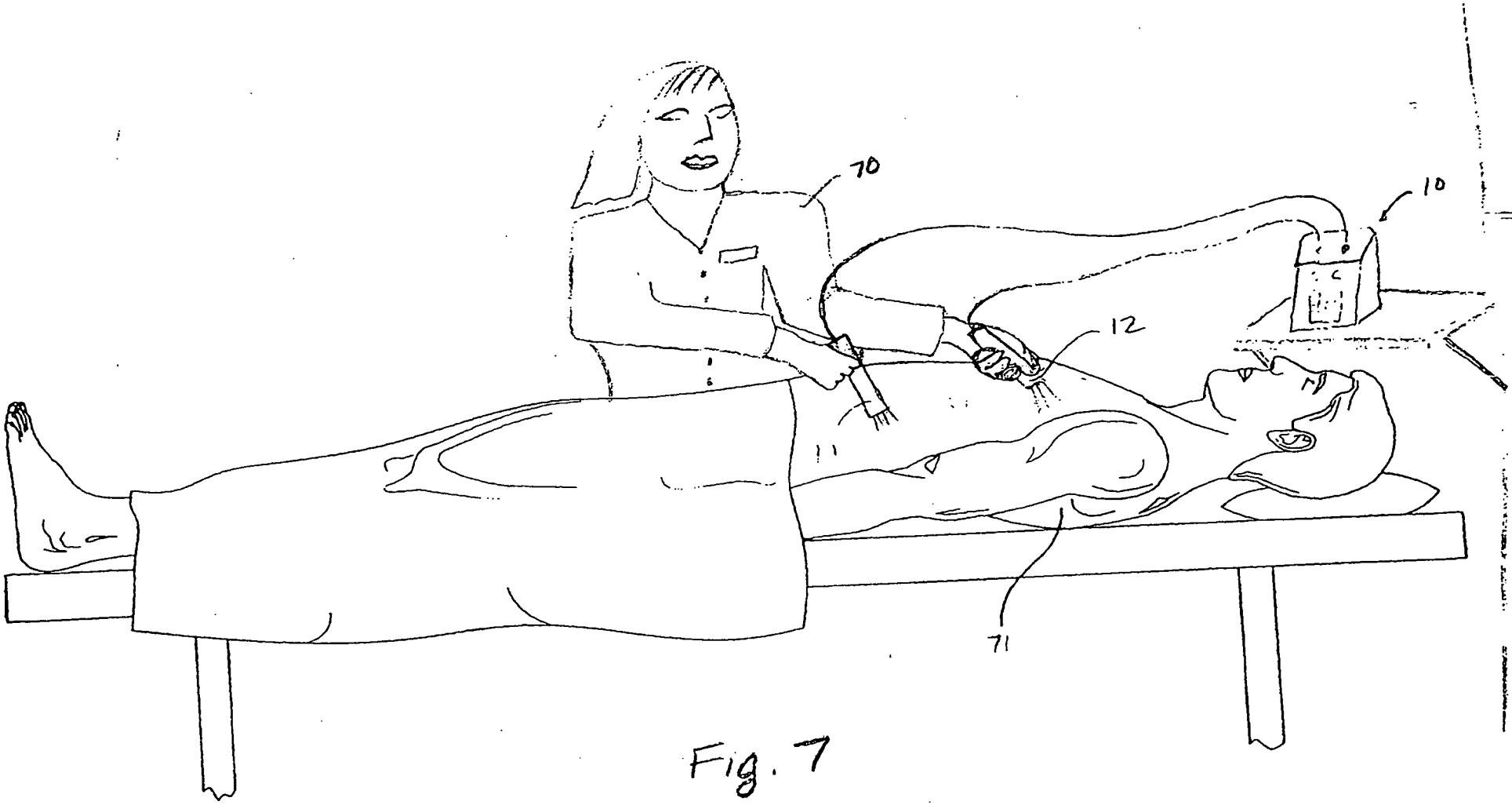

Fig. 7